SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA-2017-0042]

RIN 0960-AG65

Revised Medical Criteria for Evaluating Digestive Disorders and Skin Disorders

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving digestive and skin disorders in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect our adjudicative experience, advances in medical knowledge, and comments we received from experts and the public in response to two advance notices of proposed rulemaking (ANPRM).

DATES: To ensure that your comments are considered, we must receive them by no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any one of three methods – Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA-2017-0042, so that we may associate your comments with the correct regulation.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. Internet: We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at http://www.regulations.gov. Use the Search function to find docket number SSA-2017-0042. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. Fax: Fax comments to (410) 966-2830.

3. Mail: Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at http://www.regulations.gov or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213, or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at http://www.socialsecurity.gov.

SUPPLEMENTARY INFORMATION:

Why are we proposing to revise the listings for digestive and skin disorders?

We last published final rules that revised the digestive disorders listings on October 19, 2007, and the skin disorders listings on June 9, 2004.[1] We are proposing these revisions to reflect our adjudicative experience, advances in medical knowledge, and comments we received from experts and the public in response to two ANPRMs.

How did we develop these proposed rules?

In developing these proposed rules:

- We published an ANPRM for digestive disorders in the Federal Register on December 12, 2007.[2] We invited the public to comment on whether we should add a digestive disorders listing based on functional limitations and, if so, what criteria we

[1] See 72 FR 59398 (2007) and 69 FR 32260 (2004).
[2] See 72 FR 70527.

should use. We received 12 comments. Ten commenters recommended adding a digestive disorders listing with functional criteria and suggested we use the same functional criteria we use in other body systems.

- We published an ANPRM for skin disorders in the Federal Register on November 10, 2009.[3] We invited the public to send us written comments and suggestions about whether and how we should revise the skin disorders listings. We received three comments.

The comments we received from these two ANPRMs informed the proposed changes in this NPRM. In developing these proposed rules, we also considered information from several other sources, including:

- Medical experts in gastroenterology and dermatology;

- Advocacy groups for people with digestive and skin disorders;

- People with digestive and skin disorders and their families;

- People who make and review disability determinations and decisions for us in State agencies, in our Office of Hearings Operations, and in our Office of Analytics, Review, and Oversight; and

[3] See 74 FR 57972, with the docket number corrected at 74 FR 62518.

- The published sources we list in the References section at the end of this preamble.

How is this NPRM organized?

Digestive Disorders Overview of Proposed Revisions

- Adult digestive disorders proposed revisions
- Child digestive disorders proposed revisions

The following chart shows the heading of the current and proposed sections of the adult introductory text and listings for digestive disorders:

Current Sections of the Adult Introductory Text and Listings for the Digestive System	Proposed Sections of the Adult Introductory Text and Listings for Digestive Disorders
Introductory Text, 5.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?
B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder?
C. How do we consider the effects of treatment?	[5.00 H.]
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 5.05?
E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?
G. How do we evaluate weight loss due to any digestive disorder?	F. How do we evaluate malnutrition due to any digestive disorder under 5.08?
[5.00 D.12.]	G. How do we evaluate digestive organ transplantation?
H. What do we mean by the phrase "consider under a disability for 1 year"?	[5.00 C.2. and G.]

[5.00 C.6.]	H. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	I. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
I. How do we evaluate impairments that do not meet one of the digestive disorder listings?	J. How do we evaluate digestive disorders that do not meet one of these listings?
Listings	
5.01 Category of Impairments, Digestive System	5.01 Category of Impairments, Digestive Disorders
5.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion	5.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
5.03 [Reserved]	5.03 [Reserved]
5.04 [Reserved]	5.04 [Reserved]
5.05 Chronic liver disease (CLD)	5.05 Chronic liver disease (CLD)
5.06 Inflammatory bowel disease (IBD)	5.06 Inflammatory bowel disease (IBD)
5.07 Short bowel syndrome (SBS)	5.07 Short bowel syndrome (SBS)
5.08 Weight loss due to any digestive disorder	5.08 Malnutrition due to any digestive disorder
5.09 Liver transplantation	5.09 Liver transplantation
	5.10 [Reserved]
	5.11 Small intestine transplantation
	5.12 Pancreas transplantation

The following chart shows the heading of the current and proposed sections of the child introductory text and listings for digestive disorders:

Current Sections of the Child Introductory Text and Listings for the Digestive System	Proposed Sections of the Child Introductory Text and Listings for Digestive Disorders
Introductory Text, 105.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?
B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder?
C. How do we consider the effects of treatment?	[105.00 J.]
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 105.05?
E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under

	105.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is short bowel syndrome (SBS), and how do we evaluate it under 105.07?
G. How do we evaluate growth failure due to any digestive disorder?	F. How do we evaluate growth failure due to any digestive disorder under 105.08?
[105.00 D.13.]	G. How do we evaluate digestive organ transplantation?
H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?	H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?
I. How do we evaluate esophageal stricture or stenosis?	I. How do we evaluate esophageal stricture or stenosis?
J. What do we mean by the phrase "consider under a disability for 1 year"?	[105.00 C.2., C.4., and G.]
[105.00 C.6.]	J. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	K. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
K. How do we evaluate impairments that do not meet one of the digestive disorder listings?	L. How do we evaluate digestive disorders that do not meet one of these listings?
<u>Listings</u>	
105.01 Category of Impairments, Digestive System	105.01 Category of Impairments, Digestive Disorders
105.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion	105.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
105.03 [Reserved]	105.03 [Reserved]
105.04 [Reserved]	105.04 [Reserved]
105.05 Chronic liver disease	105.05 Chronic liver disease (CLD)
105.06 Inflammatory bowel disease (IBD)	105.06 Inflammatory bowel disease (IBD)
105.07 Short bowel syndrome (SBS)	105.07 Short bowel syndrome (SBS)
105.08 Growth failure due to any digestive disorder	105.08 Growth failure due to any digestive disorder
105.09 Liver transplantation	105.09 Liver transplantation
105.10 Need for supplemental daily enteral feeding via a gastrostomy	105.10 Need for supplemental daily enteral feeding via a gastrostomy
	105.11 Small intestine transplantation
	105.12 Pancreas transplantation

Skin Disorders Overview of Proposed Revisions

- Adult skin disorders proposed revisions

- Child skin disorders proposed revisions

The following chart shows the heading of the current and proposed sections of the adult introductory text and listings for skin disorders:

Current Sections of the Adult Introductory Text and Listings for Skin Disorders	Proposed Sections of the Adult Introductory Text and Listings for Skin Disorders
Introductory Text, 8.00	
A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 8.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 8.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	G. How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	H. How do we evaluate disorders in other body systems that affect the skin?
I. -	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
8.01 Category of Impairments, Skin Disorders	8.01 Category of Impairments, Skin Disorders
8.02 Ichthyosis	8.02 [Reserved]
8.03 Bullous disease	8.03 [Reserved]
8.04 Chronic infections of the skin or mucous membranes	8.04 [Reserved]
8.05 Dermatitis	8.05 [Reserved]
8.06 Hidradenitis suppurativa	8.06 [Reserved]
8.07 Genetic photosensitivity disorders	8.07 Genetic photosensitivity disorders
8.08 Burns	8.08 Burns

	8.09 Chronic conditions of the skin or mucous membranes

The following chart shows the heading of the current and proposed sections of the child introductory text and listings for skin disorders:

Current Sections of the Child Introductory Text and Listings for Skin Disorders	Proposed Sections of the Child Introductory Text and Listings for Skin Disorders
Introductory Text, 108.00	
A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 108.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 108.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	G. How do we evaluate chronic conditions of the skin or mucous membranes under 108.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	H. How do we evaluate disorders in other body systems that affect the skin?
I. -	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
108.01 Category of Impairments, Skin Disorders	108.01 Category of Impairments, Skin Disorders
108.02 Ichthyosis	108.02 [Reserved]
108.03 Bullous disease	108.03 [Reserved]
108.04 Chronic infections of the skin or mucous membranes	108.04 [Reserved]
108.05 Dermatitis	108.05 [Reserved]
108.06 Hidradenitis suppurativa	108.06 [Reserved]
108.07 Genetic photosensitivity disorders	108.07 Genetic photosensitivity disorders
108.08 Burns	108.08 Burns

	108.09 Chronic conditions of the skin or mucous membranes

What revisions are we proposing for digestive disorders?

We propose to:

- Change the name of the body system from "Digestive System" to "Digestive Disorders" to be consistent with the nomenclature of all body systems;

- Revise and reorganize the introductory text to provide guidance for using the revised criteria in listings;

- Revise the SSA Chronic Liver Disease (SSA CLD) score in listings 5.05 and 105.05;

- Add criteria to listings 5.06 and 105.06 for repeated complications of IBD;

- Add adult and child listings for small intestine transplantation (proposed 5.11 and 105.11) and pancreas transplantation (proposed 5.12 and 105.12); and

- Make minor editorial revisions to the introductory text and listings for clarity.

Proposed 5.00—Introductory Text to the Adult Digestive Disorders Listings

The following describes changes we are proposing to the introductory text.

Proposed 5.00C—What is chronic liver disease (CLD), and how do we evaluate it under 5.05?

We propose to:

- Redesignate current 5.00C (How do we consider the effects of treatment?) as proposed 5.00H and remove some of the guidance in current 5.00C (paragraphs 1 through C4) because the guidance is a restatement of general policy on how we consider the effects of treatment that is not unique to digestive disorders but applicable to all medically determinable impairments;

- Redesignate current 5.00D (How do we evaluate chronic liver disease?) as proposed 5.00C;

- Remove the discussion of hepatitis B and C in current 5.00D4 (Chronic viral hepatitis infections) because it does not contain guidance on evaluating CLD and continue to evaluate CLD resulting from hepatitis B and C under proposed listing 5.05;

- In 5.00C2, incorporate the information about CLD manifestations that is in current 5.00D3 (Manifestations of chronic liver disease) and 5.00D5 through 5.00D10

(Gastrointestinal hemorrhage, Ascites or hydrothorax, Spontaneous bacterial peritonitis, Hepatorenal syndrome, Hepatopulmonary syndrome, and Hepatic encephalopathy), provide guidance on how to assess the severity of these manifestations, and include the guidance in current 5.00H (What do we mean by the phrase "consider under a disability for 1 year"?); and

- In 5.00C3, incorporate the information about the SSA CLD score calculation in current 5.00D11 (End stage liver disease (ESLD) documented by scores from the SSA Chronic Liver Disease (SSA CLD) calculation) and add an SSA CLD calculation example.

Proposed 5.00D—What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?

We propose to redesignate current 5.00E (How do we evaluate inflammatory bowel disease?) as proposed 5.00D. We would describe the factors we consider when we evaluate impaired functioning due to IBD under proposed 5.06C. We would also define "marked" limitation and explain the three areas of functioning we use in the proposed listing.

Proposed 5.00E—What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?

We propose to redesignate current 5.00F (How do we evaluate short bowel syndrome?) as proposed 5.00E. We would also remove text about long-term complications of SBS because this content, while not incorrect, is not necessary to understand in order to evaluate SBS under 5.07.

Proposed 5.00F—How do we evaluate malnutrition due to any digestive disorder under 5.08?

We propose to redesignate current 5.00G (How do we evaluate weight loss due to any digestive disorder?) as proposed 5.00F. We would also use the term "malnutrition" instead of "weight loss," and clarify that weight loss must be the result of malnutrition caused by a digestive disorder.

Proposed 5.00G—How do we evaluate digestive organ transplantation?

We propose to incorporate the guidance in current 5.00D12 (Liver transplantation), and the guidance in 5.00H (What do we mean by the phrase "consider under a disability for 1 year"?), in proposed 5.00G.

Proposed 5.00H—How do we evaluate your digestive disorder if there is no record of ongoing treatment?

In proposed 5.00H, we incorporate the guidance in current 5.00C6, which explains what we do when there is no record of ongoing treatment. As we explained earlier, we removed the guidance in current 5.00C (paragraphs 1 through 4) because this the guidance is a restatement of general policy on how we consider the effects of treatment that is not unique to digestive disorders but applicable to all medically determinable impairments.

Proposed 5.00I—How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?

In proposed 5.00I, we incorporate by reference our regulations for determining whether drug addiction or alcoholism is a contributing factor material to the determination of disability because use of drugs or alcohol may result in a chronic digestive disorder, such as drug-induced hepatitis or alcoholic liver disease.

Proposed 5.00J—How do we evaluate digestive disorders that do not meet one of these listings?

We propose to redesignate current 5.00I (How do we evaluate impairments that do not meet one of the digestive disorder listings?) as proposed 5.00J.

Proposed Changes to the Adult Digestive Disorders Listings

Proposed Listing 5.02—Gastrointestinal Hemorrhaging from Any Cause

We propose to change the period during which the criteria in listing 5.02 must occur from a "6-month period" to a "12-month period" to be consistent with the timeframe criteria in all other body systems within the listings.

Proposed Listing 5.05—Chronic Liver Disease (CLD)

In 5.05A, we propose to clarify the requirement for documenting hemodynamic instability by moving the list of signs of hemodynamic instability from current 5.00D5 (Gastrointestinal hemorrhage) to proposed 5.05A. In 5.05B (Ascites or hydrothorax), we propose to change the period during which ascites or hydrothorax must occur from a "6-month period" to a "12-month period" to be consistent with the timeframe criteria in all other body systems within the listings.

In 5.05E1 (Hepatopulmonary syndrome documented by arterial P_aO_2), we propose to add "measured by an ABG test, while at rest, breathing room air, less than or equal to" to clarify our requirements for a P_aO_2 measurement. In 5.05G (SSA CLD scores), we propose to change the SSA CLD score requirement from "22 or greater" to "at least 20." A score of at least 20 accurately identifies advanced, end stage liver disease that will prevent a person from engaging in any gainful activity or will lead to death.[4] [5] [6] [7] We also

[4] Annamalai, A., Harada, M., Chen, M., Tran, T., Ko, A., Ley, E., ... Noureddin, M. (2016). Predictors of mortality in the critically ill cirrhotic patient: Is the model for end-stage liver disease enough? Journal of the American College of Surgeons, 224(3), 276-282. doi:10.1016/j.jamcollsurg.2016.11.005

propose to remove the term "end stage liver disease" because the evidence we require in order for us to consider chronic liver disease under 5.05G does not need to include the term "end stage liver disease" (which may also be referred to as "chronic liver failure").

Proposed Listing 5.06—Inflammatory Bowel Disease (IBD)

We propose to remove the low hemoglobin, low serum albumin, and weight loss criteria, which indicate malnutrition, in current 5.06 because we will evaluate those criteria under proposed 5.08 (Malnutrition due to any digestive disorder). In 5.06A (Obstruction of stenotic areas) and 5.06B (Combination of clinical findings), we propose to change the period during which the listing criteria must occur from a "6-month period" to a "12-month period" to be consistent with the timeframe criteria in all other body systems within the listings.

We also propose to add a criterion (proposed 5.06C) for repeated complications of IBD that result in marked limitation in at least one area of functioning. These criteria characterize complications of IBD that prevent a person from engaging in any gainful activity.[8] [9] [10] [11] This proposed listing combines medical criteria with specific limitations

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[5] Zhiang, E., Zhang, Z., Want, S., Xiao, Z., Gu, J., Xiong, M., ... Huang, Z. (2016). Predicting the severity of liver cirrhosis through clinical parameters. Journal of Surgical Research, 204(2), 274-281. doi:10.1016/j.jss.2016.04.036

[6] Singal, A. K. & Kamath, P. S. (2013). Model for end-stage liver disease. Journal of Clinical and Experimental Hepatology, 3(1), 50-60. doi:10.1016/j.jceh.2012.11.002

[7] Bittermann, T., Makar, G., & Goldberg, D. S. (2015). Early post-transplant survival: Interaction of MELD score and hospitalization status. Journal of Hepatology, 63(3), 601-608. doi:10.1016/j.jhep.2015.03.034

[8] Farraye, F. A., Melmed, G. Y., Lichtenstein, G. R., & Kane, S. V. (2017). ACG clinical guidelines: Preventative care in inflammatory bowel disease. American Journal of Gastroenterology, 112(2), 241-258.

[9] Gajendran, M., Loganathan, P., Catinella, A. P., & Hashash, J. G. (2018). A comprehensive review and update on Crohn's disease. Disease-a-Month, 64, 20-57.

in functioning to identify IBD of listing-level severity. The addition of functional criteria is also consistent with the listings that already include these same functional criteria, which are 7.18 (Repeated complications of hematological disorders), 14.02B (Repeated manifestations of systemic lupus erythematosus), 14.04D (Repeated manifestations of systemic sclerosis), 14.05E (Repeated manifestations of polymyositis or dermatomyositis), 14.06B (Repeated manifestations of undifferentiated or mixed connective tissue disease), 14.07C (Repeated manifestations of an immune deficiency disorder), 14.09D (Repeated manifestations of inflammatory arthritis), 14.10B (Sjögren's syndrome), and 14.11I (Repeated manifestations of HIV infection).

Proposed Listing 5.07—Short Bowel Syndrome (SBS)

We propose to require "surgical resection of any amount of the small intestine" instead of "surgical resection of more than one-half of the small intestine" because measurement of the total length of remaining intestine within the abdominal cavity is rarely obtained during surgery.[12] [13] [14]

Proposed Listing 5.08—Malnutrition Due to Any Digestive Disorder

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[10] Rubin, D. T., Ananthakrishnan, A. N., Siegel, C. A., Sauer, B. G., & Long, M. D. (2019). ACG clinical guidelines: Ulcerative colitis in adults. American Journal of Gastroenterology, 114(3), 384-413.
[11] Yarur, A. J., Strobel, S. G., Deshpande, A. R., & Abreu, M. T. (2011). Predictors of aggressive inflammatory bowel disease. Gastroenterology & Hepatology, 7(10), 652-659.
[12] Eca, R. & Barbosa, E. (2016). Short bowel syndrome: treatment options. Journal of Coloproctology, 36(4), 262-272. doi:10.1016/j.jcol.2013.07.002
[13] Hommel, M. J., van Baren, R., & Haveman, J. W. (2016). Surgical management and autologous intestinal reconstruction in short bowel syndrome. Best Practice & Research Clinical Gastroenterology, 30(2), 263-280. doi:10.1016/j.bpg.2016.03.006
[14] Wong, T. & Gupte, G. (2015). Complications of short bowel syndrome. Paediatrics and Child Health, 25(9), 418-421. doi:10.1016/j.paed.2015.07.001

We propose to revise the heading of current 5.08 from "Weight loss due to any digestive disorder" to "Malnutrition due to any digestive disorder," and revise the body mass index (BMI) measurement from "less than 17.5" to "less than 18.0." We also propose to include the criteria for low hemoglobin, low serum albumin, and the need for supplemental daily enteral or parenteral nutrition, which are in current 5.06B. These criteria are findings indicative of malnutrition, which may result from any digestive disorder, not just IBD. The combination of low BMI measurements and one of these other findings improves the specificity of listing 5.08.[15] Lastly, we propose to change the period during which the listing criteria must occur from a "6-month period" to a "12-month period" to be consistent with the timeframe criteria in all other body systems within the listings.

Proposed Digestive Organ Transplantation Listings

We propose to add listing 5.11 for small intestine transplantation and listing 5.12 for pancreas transplantation.[16] [17] We currently evaluate small intestine and pancreas transplantations under listing 5.09 for liver transplantation using our medical equivalence rules. The separate listings would allow us to differentiate which digestive organ has been

[15] Naldi, M., Baldassarre, M., Domenicali, M., Bartolini, M., & Caraceni, P. (2017). Structural and functional integrity of human serum albumin: Analytical approaches and clinical relevance in patients with liver cirrhosis. Journal of Pharmaceutical and Biomedical Analysis, 144, 138-153. doi.org/10.1016/j.jpba.2017.04.023

[16] Dholakia, S., Mittal, S., Quiroga, I., Gilbert, J., Sharples, E. J., Ploeg, R. J., & Friend, P. J. (2016). Pancreas transplantation: Past, present, future. The American Journal of Medicine, 129(7), 667-673. doi:10.1016/j.amjmed.2016.02.011

[17] Hommel, M. J., van Baren, R., & Haveman, J. W. (2016). Surgical management and autologous intestinal reconstruction in short bowel syndrome. Best Practice & Research Clinical Gastroenterology, 30(2), 263-280. doi:10.1016/j.bpg.2016.03.006

transplanted and allow us to propose future updates to each separate listing, as needed, based on medical advances in the specific organ transplant category.

Proposed 105.00—Introductory Text to the Child Digestive Disorders Listings

We repeat much of the introductory text of proposed 5.00 in the introductory text of proposed 105.00. This repetition is because the same basic rules apply for evaluating digestive disorders in adults and in children.

Proposed Changes to the Child Digestive Disorders Listings

We are proposing changes in the child listings to correspond with the changes we are proposing in the adult listings. The reasons we gave earlier for changing or removing current criteria for adults also apply to the criteria for children. Additionally, the numbering of the child listings would conform to the adult listings.

What revisions are we proposing for skin disorders?

We propose to:

- Revise and reorganize the introductory text to provide guidance for using the revised criteria in listings;

- Remove and reserve current adult listings 8.02 (Ichthyosis), 8.03 (Bullous disease), 8.04 (Chronic infections of the skin or mucous membranes), 8.05 (Dermatitis), and 8.06 (Hidradenitis suppurativa) and consolidate the current criteria into one listing for chronic conditions of the skin or mucous membranes (proposed 8.09), and remove and reserve current child listings 108.02 (Ichthyosis), 108.03 (Bullous disease), 108.04 (Chronic infections of the skin or mucous membranes), 108.05 (Dermatitis), and 108.06 (Hidradenitis suppurativa) and consolidate the current criteria into one listing for chronic conditions of the skin or mucous membranes (proposed 108.09), to strengthen adjudicative ease and more efficiently capture adults and children with skin disorders of listing-level severity;

- Include limitations of physical functioning we use to assess impairment severity, which are explained in current 8.00C and 108.00C (How do we assess the severity of your skin disorder(s)?), in the listing criteria for adult listings 8.07B (Other genetic photosensitivity disorders), 8.08 (Burns), and 8.09 (Chronic conditions of the skin or mucous membranes) and child listings 108.07B (Other genetic photosensitivity disorders), 108.08 (Burns), and 108.09 (Chronic conditions of the skin or mucous membranes); and

- Make minor editorial revisions to the introductory text and listings for clarity.

Proposed 8.00—Introductory Text to the Adult Skin Disorders Listings

Most of the guidance in the proposed introductory text is substantively the same as the guidance in the current introductory text. The following is a detailed description of the significant changes we are proposing to the introductory text. In addition to the changes we describe below, we are proposing other, minor changes to the introductory text to clarify how we use the proposed listings to evaluate skin disorders.

Proposed 8.00B—What are our definitions for the following terms used in this body system?

In this new section, 8.00B, we provide definitions for terms, such as "chronic skin lesions" and "contractures," that we use in the listings to evaluate skin disorders.

Proposed 8.00C—What evidence do we need to evaluate your skin disorder?

In 8.00C, we incorporate the guidance in current 8.00B (What documentation do we need?).

Proposed 8.00D—How do we evaluate the severity of skin disorders?

In 8.00D, we discuss how we evaluate the severity of skin disorders (which is now contained in current 8.00C) and add a clearer explanation for how we quantify limitations in functioning under these listings. In 8.00D1, we explain how we evaluate the severity of skin disorders based on the site(s) of the lesions or contractures and the

response to treatment. In 8.00D2, we explain the functional criteria we use to evaluate skin disorders under proposed 8.07B (Other genetic photosensitivity disorders), 8.08 (Burns), and 8.09 (Chronic conditions of the skin or mucous membranes). Chronic skin lesions or contractures may restrict movement and result in limitation(s) of physical functioning (ability to use the upper extremities, stand up from a seated position, or maintain an upright position while standing or walking). In 8.00D3, we propose to replace the term "flare-ups" with "exacerbations."

In 8.00D4, we propose to incorporate the guidance on symptoms in current 8.00C3 (Symptoms (including pain)). In 8.00D5, we propose to incorporate and revise the guidance on treatment in current 8.00D4 (Disfigurement or deformity) and 8.00G (How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?). We propose to replace the term "continuing treatment as prescribed" with "adherence to prescribed medical treatment" to be consistent with current medical terminology. In 8.00D5b, we provide guidance on how to evaluate skin disorders after adherence to prescribed medical treatment for 3 months.

In 8.00D5c, we provide guidance on how to evaluate claims in which the prescribed medical treatment is psoralen and ultraviolet A light (PUVA) or biologics. PUVA is a treatment involving exposure to UVA light after taking a biologic medication called psoralen that increases the skin's sensitivity to ultraviolet light. PUVA is generally used under medical supervision when other conservative treatments for skin disorders

have proven to be ineffective.[18] [19] [20] [21] We explain that, if a person receives PUVA or biologics, we will defer adjudication until 6 months from the start of treatment unless we can make a fully favorable determination or decision on another basis. In 8.00D6, we clarify how we evaluate cases in which there is no longitudinal record of ongoing treatment.

Proposed 8.00E—How do we evaluate genetic photosensitivity disorders under 8.07?

In 8.00E3, we explain that we will not purchase genetic testing, but will consider the results of this testing if it is in a person's case record. In 8.00E4, we include what the phrase "inability to function outside of a highly protective environment" means, which is in current 8.00E2 (Other genetic photosensitivity disorders).

Proposed 8.00F—How do we evaluate burns under 8.08?

In 8.00F, we include guidance for evaluating third-degree burns resulting in contractures that have been documented by an acceptable medical source to have reached maximum therapeutic benefit.

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[19] Ong, S., & Venning, V. (2014). PUVA treatment information for patients. Retrieved from Oxford University Hospital NHS website: https://www.ouh.nhs.uk/patient-guide/leaflets/files/120719puva.pdf

[20] Shenoi, S. D., & Prabhu, S. (2014). Photochemotherapy (PUVA) in psoriasis and vitiligo. Indian Journal of Dermatology, Venereology and Leprology, 80(6), 497-504. doi:10.4103/0378-6323.144143

[21] Weber, F., Schmuth, M., Seep, N., & Fritsch, P. (2005). Bath-water PUVA therapy with 8-methoxypsoralen in mycosis fungoides. Acta Dermato-Venereologica, 85, 329-332. doi:10.1080/00015550510032814

Proposed 8.00G—How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?

In 8.00G, we provide examples of the skin disorders we evaluate under new listing 8.09, which include ichthyosis, bullous diseases, chronic skin infections, dermatitis, and hidradenitis suppurativa.

Proposed 8.00H—How do we evaluate disorders in other body systems that affect the skin?

In 8.00H, we include the guidance in current 8.00D (How do we assess impairments that may affect the skin and other body systems?). We also propose to include a new paragraph (8.00H1) on evaluating skin disorders that are complications of diabetes mellitus.

Proposed 8.00I—How do we evaluate skin disorders that do not meet one of these listings?

In 8.00I, we include the guidance in current 8.00H (How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?).

Proposed Changes to the Adult Skin Disorders Listings

Proposed Listing 8.07—Genetic Photosensitivity Disorders

We propose to include the functional criteria, which we explain above, directly in 8.07B to evaluate limitation of physical functioning due to a genetic photosensitivity disorder. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed Listing 8.08—Burns

We propose to include the functional criteria, which we explain above, directly in 8.08 to evaluate limitation of physical functioning due to burns. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed Listing 8.09—Chronic Conditions of the Skin or Mucous Membranes

We propose to remove and reserve current listings 8.02 (Ichthyosis), 8.03 (Bullous disease), 8.04 (Chronic infections of the skin or mucous membranes), 8.05 (Dermatitis), and 8.06 (Hidradenitis suppurativa) and add listing 8.09 to evaluate these skin disorders. The criteria in the current listings are identical for each type of skin

disorder, and all of the named disorders are chronic conditions of the skin or mucous membranes. In proposed 8.09, we propose to include the functional criteria, which we explain above, to evaluate limitation in physical functioning due to these skin disorders. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed 108.00—Introductory Text to the Child Skin Disorders Listings

We repeat much of the introductory text of proposed 8.00 in the introductory text of proposed 108.00. This repetition is because the same basic rules apply for evaluating skin disorders in adults also apply to skin disorders in children with one exception – how we evaluate limitation of physical functioning. Children's physical abilities change as they grow and mature. For example, young infants are not able to walk, but do move their extremities and may use them to roll over, crawl, or perform other functions as they develop. To evaluate the severity of skin disorders in children, we propose to use criteria based on a child's ability to independently initiate, sustain, and complete age-appropriate activities.

Proposed Changes to the Child Skin Disorders Listings

We are proposing changes in the child listings to correspond with the changes we are proposing in the adult listings. Other changes are specific to how we evaluate skin

disorders in children. The reasons we gave earlier for changing or removing current criteria for adults also apply to the criteria for children. Additionally, the numbering of the child listings would conform to that of the adult listings.

Other Questions

We are interested in receiving public comments on the following topics:

- Are there any digestive or skin disorders that meet one of the proposed listings, but are generally expected to medically improve after a certain amount of time to the point at which the disorders are no longer of listing-level severity? If you believe there are digestive or skin disorders that fit into this category, please tell us by submitting your comments and any supporting research or data on that issue.

- Do the proposed rules for evaluating chronic conditions of the skin or mucous membranes (conditions such as psoriasis and hidradenitis suppurativa) appropriately consider whether treatment regimens interfere with the ability to do any work? If you believe the criteria should be revised, please tell us by submitting your comments and any supporting research or data.

- Should any of the proposed listings for either digestive disorders or skin disorders be combined into one listing or divided into multiple listings to strengthen

adjudicative ease and capture adults or children with impairments that are of listing-level severity?

- Based on advances in medical functional restorative treatment of many skin disorders, is our proposal for the durations of persistent treatment appropriate for listing-level severity? Specifically, the current listings for chronic skin infections require that claimants be considered for listing-level severity if exacerbations persist despite adherence to prescribed medical treatment for three months, unless we can make a fully favorable determination or decision on another basis. We propose that, for claimants who have access to treatment with PUVA or biologics, the skin disorder be considered for listing-level severity if exacerbations persist despite treatment for six months from the start of PUVA or biologics. Alternatively, for burns, we propose that, for consideration of listing-level severity, an acceptable medical source document maximum therapeutic benefit and, therefore, a claimant is no longer receiving surgical management. Do these criteria create incentive to not seek medical treatment in order to obtain or maintain access to disability benefits? If you believe the criteria for skin disorder treatment duration should be revised, please tell us by submitting your comments and any supporting research or data.

<u>What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?</u>

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.[22]

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Rulemaking Analyses and Notices

We will consider all comments we receive on or before the close of business on the comment closing date indicated above. The comments will be available for examination in the rulemaking docket for these rules at the above address. We will file comments received after the comment closing date in the docket and will consider those comments to the extent practicable. However, we will not respond specifically to untimely comments. We may publish a final rule at any time after close of the comment period.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments

[22] Sections 205(a), 702(a)(5), and 1631(d)(1).

on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand; e.g., grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these proposed rules until we evaluate public comments and publish final rules in the Federal Register. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of the relevant comments we received and an explanation of how we will apply the new rules.

REGULATORY PROCEDURES

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed them.

We also determined that these proposed rules meet the plain language requirement of Executive Order 12866.

Executive Order 13132 (Federalism)

We analyzed these proposed rules in accordance with the principles and criteria established by Executive Order 13132, and determined that these proposed rules will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that these proposed rules will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect individuals only.

Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Executive Order 13771

Anticipated Accounting Costs of These Proposed Rules

Anticipated Costs to Our Programs

Our Office of the Chief Actuary estimates, based on the best available data, that this proposed rule, assuming it is finalized and implemented for all disability decisions completed after February 1, 2020, would result in a reduction of $155 million in OASDI benefit payments and a reduction of $55 million in Federal SSI payments over the 10-year period of FY 2019-2028.

Anticipated Administrative Costs to the Social Security Administration

The Office of Budget, Finance, and Management estimated administrative savings of less than 15 work years and $2 million annually, which we consider to be a non-significant amount.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

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We consulted the following references when we developed these proposed rules:

Digestive Disorders

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We will make these references available to you for inspection if you are interested in reading them. Please make arrangements with the contact person shown in this preamble if you would like to review any reference materials.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, survivors, and disability insurance, Reporting and recordkeeping requirements, Social Security.

Andrew Saul,
Commissioner of Social Security.

For the reasons set forth in the preamble, we propose to amend subpart P of part 404 of title 20 of the Code of Federal Regulations as set forth below:

Part 404--FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart P—Determining Disability and Blindness

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)-(h), 216(i), 221(a) and (h)-(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)-(h), 416(i), 421(a) and (h)-(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104-193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108-203, 118 Stat. 509 (42 U.S.C. 902 note).

2. Amend appendix 1 to subpart P of part 404 as follows:

a. Revise items 6 and 9 of the introductory text before part A;

b. In part A, revise the body system name for section 5.00 in the table of contents and sections 5.00 and 8.00; and

c. In part B, revise the body system name for section 105.00 in the table of contents and sections 105.00 and 108.00.

The revisions read as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

6. Digestive Disorders (5.00 and 105.00) [date 5 years from the effective date of the final rule].

* * * * *

9. Skin Disorders (8.00 and 108.00) [date 5 years from the effective date of the final rule].

* * * * *

Part A

* * * * *

5.00 Digestive Disorders

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5.00 DIGESTIVE DISORDERS

A. Which digestive disorders do we evaluate in this body system? We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of such disorders and the listings we use to evaluate them include chronic liver disease (5.05), inflammatory bowel disease (5.06), and short bowel syndrome (5.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (5.02), malnutrition due to any digestive disorder (5.08), liver transplantation (5.09), small intestine transplantation (5.11), and pancreas transplantation (5.12). We evaluate cancers affecting the digestive system under the listings in 13.00.

B. What evidence do we need to evaluate your digestive disorder?

1. General. To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. Laboratory findings. We need laboratory reports such as results of imaging (see 5.00B3), endoscopy, and other diagnostic procedures. We may also need clinical laboratory and pathology results.

3. Imaging refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. What is chronic liver disease (CLD), and how do we evaluate it under 5.05?

1. General. CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in adults include chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV), and prolonged alcohol abuse.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, or altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, or sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 5.05.

b. Laboratory findings of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had

a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. Manifestations of CLD.

a. Gastrointestinal hemorrhaging (5.05A), as a consequence of cirrhosis and high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 5.02. The phrase "consider under a disability for 1 year" in 5.02 and 5.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. Ascites or hydrothorax (5.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. Spontaneous bacterial peritonitis (SBP) (5.05C) is an acute bacterial infection of peritoneal fluid, and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 5.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. Hepatorenal syndrome (5.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria (reduced output of urine). We evaluate renal dysfunction with known underlying kidney pathology, such as glomerulonephritis, tubular necrosis, and renal infections under the listings in 6.00.

e. Hepatopulmonary syndrome (5.05E) is arterial deoxygenation (hypoxemia) due to intrapulmonary vascular dilation and arteriovenous shunting, associated with CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 3.00.

(i) Under 5.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the

altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 5.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. Hepatic encephalopathy (5.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 5.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium, or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic encephalopathy when not attributable to other causes may include a "flapping tremor" (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however,

if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 5.05F.

(iii) We will not evaluate acute encephalopathy under 5.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 11.00 and acute encephalopathy caused by cancer under the listings in 13.00.

3. SSA CLD score (5.05G). Listing 5.05G requires two SSA CLD scores, each requiring three laboratory values. The "date of the SSA CLD score" is the date of the earliest of the three laboratory values used for its calculation. The date of the second SSA CLD score must be at least 60 days after the date of the first SSA CLD score and both scores must be within the required 12-month period.

a. We calculate the SSA CLD score using a formula that includes three laboratory values: serum creatinine (mg/dL), total bilirubin (mg/dL), and INR. The formula for the SSA CLD score calculation is:

$$9.57 \times [\log_e(\text{serum creatinine mg/dL})] + 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] + 11.2 \times [\log_e(\text{INR})] + 6.43$$

b. When we indicate "$\log_e$" (also abbreviated "ln") in the formula for the SSA CLD score calculation, we mean the "base e logarithm" or "natural logarithm" of the

numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 2.0 mg/dL, serum total bilirubin 1.5 mg/dL, and INR 1.0, we compute the SSA CLD score as follows:

$9.57 \times [\log_e(\text{serum creatinine } 2.0 \text{ mg/dL}) = 0.693]$
$+ 3.78 \times [\log_e(\text{serum total bilirubin } 1.5 \text{ mg/dL}) = 0.405]$
$+11.2 \times [\log_e(\text{INR } 1.0) = 0]$
$+ 6.43$
$= 6.63 + 1.53 + 0 + 6.43$
$= 14.6$, which we round to an SSA CLD score of 15.

c. For any SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, and INR) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the highest value to calculate your SSA CLD score. If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD calculation. We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

D. What is inflammatory bowel disease (IBD), and how do we evaluate it under

5.06?

1. IBD is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, and palpable abdominal mass (usually inflamed loops of bowel), when we assess the severity of your impairment(s).

3. We consider other signs or laboratory findings of IBD that indicate malnutrition, such as anemia, edema, weight loss, or hypoalbuminemia, when we determine your ability to maintain adequate nutrition. We evaluate your inability to maintain adequate nutrition under 5.08.

4. Repeated complications of IBD.

a. Examples of complications of IBD include abscesses, intestinal perforation, toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism). When we evaluate repeated complications of IBD, we consider all relevant information in your case record to determine the effects of your IBD on your ability to

function independently, appropriately, effectively, and on a sustained basis. Factors we consider include, but are not limited to: your symptoms, the frequency and duration of your complications, periods of exacerbation and remission, and the functional effects of your treatment, including the side effects of your medication. Your impairment will satisfy this criterion regardless of whether you have the same kind of complication repeatedly, all different complications, or any other combination of complications; for example, two of the same kind of complication and a different one.

b. To satisfy the requirements described under 5.06C, your IBD must result in repeated complications and marked limitation in one of three areas of functioning: activities of daily living; maintaining social functioning; or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. If the complications do not last as long or occur as frequently as required under 5.06C, we will consider whether your IBD medically equals the listing.

c. Marked limitation means that the signs and symptoms of your IBD interfere seriously with your ability to function. Although we do not require the use of such a scale, "marked" would be the fourth point on a five-point rating scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. We do not define "marked" by a specific number of activities of daily living or different behaviors in which your social functioning is impaired, or a specific number of tasks that you are able to complete, but by the nature and overall degree of interference with your functioning. You may have marked limitation when several activities or

functions are impaired, or when only one is impaired. Additionally, you need not be totally precluded from performing an activity to have marked limitation, as long as the degree of limitation interferes seriously with your ability to function independently, appropriately, and effectively. The term "marked" does not imply that you must be confined to bed, hospitalized, or in a nursing home.

d. Activities of daily living include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills. We will find that you have "marked" limitation in activities of daily living if you have a serious limitation in your ability to maintain a household or take public transportation because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to perform some self-care activities.

e. Maintaining social functioning includes the capacity to interact independently, appropriately, effectively, and on a sustained basis with others. It includes the ability to communicate effectively with others. We will find that you have "marked" limitation in maintaining social functioning if you have a serious limitation in social interaction on a sustained basis because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, or a pattern of exacerbation and remission, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to communicate with close friends or relatives.

f. Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. We will find that you have "marked" limitation in completing tasks if you have a serious limitation in your ability to sustain concentration or pace adequate to complete work-related tasks because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to do some routine activities of daily living.

E. What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?

1. SBS is a malabsorption disorder that occurs when ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

2. We require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

F. How do we evaluate malnutrition due to any digestive disorder under 5.08?

1. We evaluate malnutrition due to any digestive disorder using two body mass index (BMI) measurements at least 60 days apart in combination with an abnormal laboratory finding. If you have more than two BMI measurements within a consecutive 12-month period, we will use your two lowest BMI measurements that are at least 60 days apart.

2. BMI is the ratio of your weight to the square of your height.

a. We use measurements of your weight and height without shoes for these calculations.

b. We calculate BMI using one of the following formulas:

English Formula

BMI = [Weight in Pounds / (Height in Inches × Height in Inches)] × 703

Metric Formulas

BMI = Weight in Kilograms / (Height in Meters × Height in Meters)

BMI = [Weight in Kilograms / (Height in Centimeters × Height in Centimeters)]

× 10,000

G. How do we evaluate digestive organ transplantation? If you receive a liver (5.09), small intestine (5.11), or pancreas (5.12) transplant, we will consider you to be disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase "consider under a disability for 1 year" in 5.09, 5.11, and 5.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. How do we evaluate your digestive disorder if there is no record of ongoing treatment? If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive disorders listing, but your impairment may medically equal a listing, or be disabling based on consideration of your residual functional capacity, age, education, and work experience.

I. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder? If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See § 404.1535 and § 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

J. How do we evaluate digestive disorders that do not meet one of these listings?

1. These listings are only examples of common digestive disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 404.1526 and § 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, you may or may not have the

residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in § 404.1520 and § 416.920 of this chapter. We use the rules in § 404.1594 and § 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

5.01 Category of Impairments, Digestive Disorders

5.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions of at least 2 units of blood per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

5.03–5.04 [Reserved]

5.05 Chronic liver disease (CLD) (see 5.00C) with A, B, C, D, E, F, or G:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 5.00C2a), documented by imaging (see 5.00B3); resulting in hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down, or syncope (fainting); and requiring hospitalization for transfusion of at least two units of blood. Consider under a disability for 1 year following the documented transfusion; after that,

evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 5.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 5.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 5.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 500 mL; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 5.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown by contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 5.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. Two SSA CLD scores (see 5.00C3) of at least 20 within a consecutive 12-month period and at least 60 days apart.

5.06 Inflammatory bowel disease (IBD) (see 5.00D) documented by endoscopy, biopsy, imaging, or operative findings, and demonstrated by A, B, or C:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

2. Perineal disease with a draining abscess or fistula; or

3. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter.

OR

C. Repeated complications of IBD (see 5.00D4a), occurring an average of three times a year, or once every 4 months, each lasting 2 weeks or more, within a consecutive 12-month period, and marked limitation (see 5.00D4c) in one of the following:

1. Activities of daily living (see 5.00D4d); or

2. Maintaining social functioning (see 5.00D4e); or

3. Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace (see 5.00D4f).

5.07 Short bowel syndrome (SBS) (see 5.00E) due to surgical resection of any amount of the small intestine, resulting in dependence on daily parenteral nutrition via a central venous catheter.

5.08 Malnutrition due to any digestive disorder (see 5.00F), documented by A and

B:

A. One of the following:

1. Anemia with hemoglobin of less than 10.0 g/dL, present on two evaluations within a consecutive 12-month period and at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on two evaluations within a consecutive 12-month period and at least 60 days apart.

AND

B. Two BMI measurements of less than 18.0 (see 5.00F2) within a consecutive 12-month period and at least 60 days apart.

5.09 Liver transplantation (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.10 [Reserved]

5.11 Small intestine transplantation (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.12 Pancreas transplantation (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

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8.00 SKIN DISORDERS

A. Which skin disorders do we evaluate under these listings? We use these listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (8.07), burns (8.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (8.09).

B. What are our definitions for the following terms used in this body system?

1. Assistive device(s): An assistive device, for the purposes of these listings, is any device used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; or worn, such as a prosthesis or an orthosis.

2. Chronic skin lesions: Chronic skin lesions can have recurrent exacerbations. They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms

of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 8.00D2.

3. Contractures: Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 8.00D2.

4. Documented medical need: When we use the term "documented medical need," we mean that there is evidence from your medical source(s) in the medical record that supports your need for an assistive device (see § 404.1513 and § 416.913 of this chapter). The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device, and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. Fine and gross movements: Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping,

holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling.

6. Surgical management: For the purposes of these listings, surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

C. What evidence do we need to evaluate your skin disorder?

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations;

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Your history of familial incidence; exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

e. Your ability to function outside of a highly protective environment;

f. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

g. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

h. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. How do we evaluate the severity of skin disorders?

1. General. We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions or contractures, functional limitations caused by your signs and symptoms (including pain) (see 8.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations, how quickly they resolve,

and how you function between exacerbations, to determine whether your skin disorder meets or medically equals a listing. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 8.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 404.1512, 404.1513, and 404.1520b and §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating your symptoms, see § 404.1529 and § 416.929 of this chapter.

2. Limitation(s) of physical functioning due to skin disorders.

a. Skin disorders may be due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete work-related activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 8.07B, 8.08, and 8.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see § 404.1509 and § 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because the characteristics and severity of the disorder itself are sufficient to meet the criteria in 8.07A.

b. The functional criteria require impairment-related physical limitations in using

upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements;

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements due to chronic skin lesions or contractures, and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. Frequency of exacerbations due to chronic skin lesions. A skin disorder

resulting in chronic skin lesions (see 8.00B2) may have frequent exacerbations severe enough to meet a listing even if each individual skin lesion exacerbation did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations; how quickly they resolve; and how you function in the time between skin lesion exacerbations, to determine whether your skin disorder meets or equals a listing.

4. Symptoms (including pain). Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing, or whether you are otherwise able to work. We consider your symptoms only when you have a medically determinable impairment that could reasonably be expected to produce the symptoms. See § 404.1529 and § 416.929 of this chapter.

5. Treatment.

a. General. Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. Despite adherence to prescribed medical treatment for 3 months. Under 8.09,

we require that your symptoms persist "despite adherence to prescribed medical treatment for 3 months." This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a physician for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, "sufficient time" means a period of at least 3 months. If your treatment has not lasted for at least 3 months, we will follow the rules in 8.00D6a. To evaluate the severity of physical limitations due to your skin disorder(s), we require medically documented evidence of disorder-related physical limitation(s) of functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months. See § 404.1509 and § 416.909 of this chapter. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics. If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. No record of ongoing treatment.

a. Despite having a skin disorder, you may not have received ongoing treatment,

may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see § 404.1519a and § 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 8.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 8.00I.

E. How do we evaluate genetic photosensitivity disorders under 8.07? Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. Xeroderma pigmentosum (XP) (8.07A). XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body's ability to repair DNA (deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 8.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 8.00E3).

2. Other genetic photosensitivity disorders (8.07B). The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 8.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 8.00C) and must result either in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that result in functional limitations (see 8.00D), or must result in the inability to function outside of a highly protective environment. Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 2.00, 11.00, 12.00, or 13.00, as appropriate.

3. What evidence do we need to document that you have XP or another genetic photosensitivity disorder? We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic laboratory test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an acceptable medical source (AMS); or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. Inability to function outside of a highly protective environment means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. How do we evaluate burns under 8.08?

1. Electrical, chemical, or thermal burns frequently affect other body systems, for

example, musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological, or mental. We evaluate burns in the same way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 8.00B6), we will evaluate your disorder under the listings in 1.00.

2. We evaluate third-degree burns resulting in contractures (see 8.00B3) that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 8.08. To be disabling, these burns must result in functional limitation(s) (see 8.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. How do we evaluate chronic conditions of the skin or mucous membranes under 8.09? We evaluate skin disorders that result in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) under 8.09. These disorders must result in chronic skin lesions or contractures that continue to persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b) and cause functional limitations (see 8.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. How do we evaluate disorders in other body systems that affect the skin?

When your disorder(s) in another body system affects the skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that may affect the skin include the following:

1. Diabetes mellitus. Diabetes mellitus that is not well controlled, despite treatment, can cause chronic hyperglycemia resulting in serious, long-lasting or recurrent exacerbations or complications. We evaluate those exacerbations or complications under the affected body system(s). If the complication involves soft tissue or amputation(s), we evaluate these features under the listings in 1.00. If the exacerbations or complications involve chronic bacterial or fungal skin lesions resulting from diabetes mellitus, we evaluate your limitations from the skin disorder under listing 8.09.

2. Tuberous sclerosis. The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disability or other mental disorders. We evaluate these features under the listings in 11.00 or 12.00, as appropriate.

3. Malignant tumors of the skin. Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 13.00.

4. Immune system disorders. We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 14.00.

5. Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders. A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 1.00, 2.00, 5.00, or 12.00, as appropriate.

I. How do we evaluate skin disorders that do not meet one of these listings?

1. These listings are only examples of common skin disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 404.1526 and § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in § 404.1520 and § 416.920 of this chapter. We use the rules in § 404.1594 and § 416.994 of this chapter, as appropriate, when we decide

whether you continue to be disabled.

8.01 Category of Impairments, Skin Disorders

8.02–8.06 [Reserved]

8.07 Genetic photosensitivity disorders, established as described in 8.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 8.00E1).

OR

B. Other genetic photosensitivity disorders (see 8.00E2) with either 1 or 2:

1. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause an inability to function outside of a highly protective environment (see 8.00E4); or

2. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause functional limitations (see 8.00D2) due to limitation(s) from your skin condition, such as pain, as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements; or

b. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.08 Burns (see 8.00F). Third-degree burns that do not require continuing surgical management, or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, resulting in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3)

that cause functional limitations (see 8.00D2) due to limitation(s), such as pain, from your skin condition, as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.09 Chronic conditions of the skin or mucous membranes (see 8.00G) resulting in:

A. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3); chronic pain; or other physical limitation(s); that persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b), causing functional limitations (see 8.00D2) due to limitation(s), such as pain, from your skin condition.

AND

B. Impairment-related significant limitation demonstrated by 1, 2, 3, or 4:

1. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements; or

2. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin

lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to the involvement of the perineum or the inguinal region).

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Part B

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105.00 Digestive Disorders

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105.00 DIGESTIVE DISORDERS

A. Which digestive disorders do we evaluate in this body system? We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of such disorders and the listings we use to evaluate them include chronic liver disease (105.05), inflammatory bowel disease (105.06), and short bowel syndrome (105.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (105.02), growth failure due to any digestive disorder (105.08), liver transplantation (105.09), need for supplemental daily enteral feeding via a gastrostomy due to any cause for children who have not attained age 3 (105.10), small intestine transplantation (105.11), and pancreas transplantation (105.12). We evaluate cancers affecting the digestive system under the listings in 113.00.

B. What evidence do we need to evaluate your digestive disorder?

1. General. To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. Laboratory findings. We need laboratory reports such as results of imaging (see 105.00B3), endoscopy, and other diagnostic procedures. We may also need clinical laboratory and pathology results.

3. Imaging refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. What is chronic liver disease (CLD), and how do we evaluate it under 105.05?

1. General. CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in children include chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV), autoimmune hepatitis, and metabolic disease.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, or altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, or sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 105.05.

b. Laboratory findings of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. Manifestations of CLD.

a. Gastrointestinal hemorrhaging (105.05A), as a consequence of cirrhosis and high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 105.02. The phrase "consider under a disability for 1 year" in 105.02 and 105.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. Ascites or hydrothorax (105.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are

portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. Spontaneous bacterial peritonitis (SBP) (105.05C) is an acute bacterial infection of peritoneal fluid, and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 105.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. Hepatorenal syndrome (105.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria (reduced output of urine). We evaluate renal dysfunction with known underlying kidney pathology, such as glomerulonephritis, tubular necrosis, and renal infections under the listings in 106.00.

e. Hepatopulmonary syndrome (105.05E) is arterial deoxygenation (hypoxemia) due to intrapulmonary vascular dilation and arteriovenous shunting, associated with CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 103.00.

(i) Under 105.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 105.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. Hepatic encephalopathy (105.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 105.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium, or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic encephalopathy when not attributable to other causes may include a "flapping tremor" (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 105.05F.

(iii) We will not evaluate acute encephalopathy under 105.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 111.00 and acute encephalopathy caused by cancer under the listings in 113.00.

3. SSA CLD and SSA CLD-P scores (105.05G). Listing 105.05G1 requires two SSA CLD scores, each requiring three laboratory values, or two SSA CLD-P scores, each requiring four parameters (three laboratory values and growth failure). The "date of the SSA CLD score" is the date of the earliest of the three laboratory values used for its calculation. The "date of the SSA CLD-P score" is the date of the earliest of the three laboratory values used for its calculation. For 105.05G1, the date of the second SSA CLD or SSA CLD-P score must be at least 60 days after the date of the first SSA CLD or SSA CLD-P score and both scores must be within the required 12-month period. Listing 105.05G2 requires one SSA CLD-P score.

a. SSA CLD score.

(i) We calculate the SSA CLD score using a formula that includes three laboratory values: serum creatinine (mg/dL), total bilirubin (mg/dL), and INR. The formula for the SSA CLD score calculation is:

$$9.57 \times [\log_e(\text{serum creatinine mg/dL})] + 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] + 11.2 \times [\log_e(\text{INR})] + 6.43$$

(ii) When we indicate "$\log_e$" (also abbreviated "ln") in the formula for the SSA CLD score calculation, we mean the "base e logarithm" or "natural logarithm" of the numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 2.0 mg/dL, serum total bilirubin 1.5 mg/dL, and INR 1.0, we compute the SSA CLD score as follows:

$$9.57 \times [\log_e(\text{serum creatinine } 2.0 \text{ mg/dL}) = 0.693] + 3.78 \times [\log_e(\text{serum total bilirubin } 1.5 \text{ mg/dL}) = 0.405] + 11.2 \times [\log_e(\text{INR } 1.0) = 0] + 6.43$$
$$= 6.63 + 1.53 + 0 + 6.43$$
$$= 14.6, \text{ which we round to an SSA CLD score of } 15.$$

(iii) For an SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, and INR) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0

up to 1.0 to calculate your SSA CLD score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the highest value to calculate your SSA CLD score. If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD calculation. We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

b. SSA CLD-P score

(i) We calculate the SSA CLD-P scores using a formula that includes four parameters: Serum total bilirubin (mg/dL), INR, serum albumin (g/dL), and whether you have growth failure. The formula for the SSA CLD-P score calculation is:

$4.80 \times [\log_e(\text{serum total bilirubin mg/dL})]$
$+ 18.57 \times [\log_e(\text{INR})]$
$- 6.87 \times [\log_e(\text{serum albumin g/dL})]$
+ 6.67 if you have growth failure (<-2 standard deviations for weight or height)

(ii) When we indicate "$\log_e$" in the formula for the SSA CLD-P score calculation, we mean the "base e logarithm" or "natural logarithm" ($\log_e$) of a numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a female child is 4.0 years old, has

growth failure, and has laboratory values of serum total bilirubin 2.2 mg/dL, INR 1.0, and serum albumin 3.5 g/dL, we compute the SSA CLD-P score as follows:

$4.80 \times [\log_e(\text{serum total bilirubin } 2.2 \text{ mg/dL}) = 0.788]$
$+ 18.57 \times [\log_e(\text{INR } 1.0) = 0]$
$- 6.87 \times [\log_e(\text{serum albumin } 3.5 \text{ g/dL}) = 1.253]$
$+ 6.67$
$= 3.78 + 0 - 8.61 + 6.67$
$= 1.84$, which we round to an SSA CLD-P score of 2.

(iii) For an SSA CLD-P score calculation, all of the required laboratory values (serum total bilirubin, INR, and serum albumin) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD-P score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the highest serum total bilirubin and INR values and the lowest serum albumin value to calculate the SSA CLD-P score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD-P calculation. We will not purchase INR values for children who have not attained age 12. If there is no INR value for a child under 12 within the applicable period, we will use an INR value of 1.1 to calculate the SSA CLD-P score. We round the results of your SSA CLD-P score calculation to the nearest whole integer to arrive at your SSA CLD-P score.

(iv) The weight and length/height measurements used for the calculation must be obtained within the same 30-day period as the laboratory values.

4. Extrahepatic biliary atresia (105.05H) presents itself in the first 2 months of life with persistent jaundice. To satisfy 105.05H, the diagnosis of extrahepatic biliary atresia must be confirmed by liver biopsy or intraoperative cholangiogram that shows obliteration of the extrahepatic biliary tree. Biliary atresia is usually treated surgically by portoenterostomy (for example, Kasai procedure). If this surgery is not performed in the first months of life or is not completely successful, liver transplantation is indicated. If you have received a liver transplant, we will evaluate your impairment under 105.09. The phrase "consider under a disability for 1 year" in 105.05H does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 105.06?

1. IBD is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, and palpable abdominal mass (usually inflamed loops of bowel), when we assess the severity of your impairment(s).

3. We consider other signs or laboratory findings of IBD that indicate malnutrition, such as anemia, edema, weight loss, or hypoalbuminemia, when we determine your ability to maintain adequate nutrition. We evaluate your inability to maintain adequate nutrition under 105.08.

4. Examples of complications of IBD that may result in hospitalization include abscesses, intestinal perforation, toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism). The three hospitalizations in 105.06C do not have to be for the same complication of IBD.

E. What is short bowel syndrome (SBS), and how do we evaluate it under 105.07?

1. SBS is a malabsorption disorder that occurs when congenital intestinal abnormalities, ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

2. We require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily

parenteral nutrition to provide most of your nutritional requirements.

F. How do we evaluate growth failure due to any digestive disorder under 105.08?

1. To evaluate growth failure due to any digestive disorder, we require documentation of the laboratory findings of chronic nutritional deficiency described in 105.08A and the growth measurements in 105.08B within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements.

2. Under 105.08B, we evaluate a child's growth failure by using the appropriate table for age and gender.

a. For children from birth to attainment of age 2, we use the weight-for-length table (see Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table (see Table III or Table IV).

c. BMI is the ratio of your weight to the square of your height. We calculate BMI using one of the following formulas:

English Formula

BMI = [Weight in Pounds / (Height in Inches × Height in Inches)] × 703

Metric Formulas

BMI = Weight in Kilograms / (Height in Meters × Height in Meters)

BMI = [Weight in Kilograms / (Height in Centimeters × Height in Centimeters)] × 10,000

G. How do we evaluate digestive organ transplantation? If you receive a liver (105.09), small intestine (105.11), or pancreas (105.12) transplant, we will consider you to be disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase "consider under a disability for 1 year" in 105.09, 105.11, and 105.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy? We evaluate the need for supplemental daily enteral feeding via a gastrostomy in children who have not attained age 3 under 105.10 regardless of the medical reason for the gastrostomy. After a child attains age 3, we evaluate growth failure due to any digestive disorder under 105.08, IBD requiring supplemental daily enteral or parenteral nutrition under 105.06, or other medical or developmental disorders under another digestive disorders listing or under a listing in an affected body system(s).

I. How do we evaluate esophageal stricture or stenosis? Esophageal stricture or stenosis (narrowing) from congenital atresia (absence or abnormal closure of a tubular body organ) or destructive esophagitis may result in malnutrition or the need for gastrostomy placement, which we evaluate under 105.08 or 105.10. Esophageal stricture or stenosis may also result in complications such as pneumonias due to frequent aspiration, or difficulty in maintaining nutritional status short of listing level severity. While these individual complications usually do not meet the listing criteria, a combination of your impairments may medically equal a listing or functionally equal the listings.

J. How do we evaluate your digestive disorder if there is no record of ongoing treatment? If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive

disorders listing, but your impairment may medically equal a listing, or be disabling based on our rules of functional equivalence.

K. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder? If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See § 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

L. How do we evaluate digestive disorders that do not meet one of these listings?

1. These listings are only examples of common digestive disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we

determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, we will also consider whether it functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

105.01 Category of Impairments, Digestive Disorders

105.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions of at least 10 cc of blood/kg of body weight per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

105.03–105.04 [Reserved]

105.05 Chronic liver disease (CLD) (see 105.00C) with A, B, C, D, E, F, G, or H:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 105.00C2a), documented by imaging (see 105.00B3); resulting in hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down, or syncope (fainting); and requiring hospitalization for transfusion of at least 10 cc of

blood/kg of body weight. Consider under a disability for 1 year following the documented transfusion; after that, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 105.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 105.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 105.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 1 mL/kg/hr; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 105.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown on contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 105.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. SSA CLD or SSA CLD-P scores (see 105.00C3):

1. For children age 12 or older, two SSA CLD or SSA CLD-P scores of at least 20 within a consecutive 12-month period and at least 60 days apart; or

2. For children who have not attained age 12, one SSA CLD-P score of at least 11.

OR

H. Extrahepatic biliary atresia as diagnosed on liver biopsy or intraoperative cholangiogram (see 105.00C4). Consider under a disability for 1 year following diagnosis; after that, evaluate the residual impairment(s).

105.06 Inflammatory bowel disease (IBD) (see 105.00D) documented by endoscopy, biopsy, imaging, or operative findings and demonstrated by A or B:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon

with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

2. Perineal disease with a draining abscess or fistula; or

3. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter (see 105.10 for children who have not attained age 3).

105.07 Short bowel syndrome (SBS) (see 105.00E) due to surgical resection of any amount of the small intestine, resulting in dependence on daily parenteral nutrition via a central venous catheter.

105.08 Growth failure due to any digestive disorder (see 105.00F), documented

by A and B:

A. Chronic nutritional deficiency present on two evaluations within a consecutive 12-month period and at least 60 days apart documented by 1 or 2:

1. Anemia with hemoglobin less than 10.0 g/dL; or

2. Serum albumin of 3.0 g/dL or less.

AND

B. Growth failure as required in 1 or 2:

1. For children from birth to attainment of age 2, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile values in Table I or Table II; or

Table I - Males Birth to Attainment of Age 2

Third Percentile Values for Weight-for-Length

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.597	64.5	6.132	84.5	10.301
45.5	1.703	65.5	6.359	85.5	10.499
46.5	1.919	66.5	6.584	86.5	10.696
47.5	2.139	67.5	6.807	87.5	10.895
48.5	2.364	68.5	7.027	88.5	11.095
49.5	2.592	69.5	7.245	89.5	11.296
50.5	2.824	70.5	7.461	90.5	11.498
51.5	3.058	71.5	7.674	91.5	11.703
52.5	3.294	72.5	7.885	92.5	11.910
53.5	3.532	73.5	8.094	93.5	12.119
54.5	3.771	74.5	8.301	94.5	12.331
55.5	4.010	75.5	8.507	95.5	12.546
56.5	4.250	76.5	8.710	96.5	12.764
57.5	4.489	77.5	8.913	97.5	12.987
58.5	4.728	78.5	9.113	98.5	13.213
59.5	4.966	79.5	9.313	99.5	13.443
60.5	5.203	80.5	9.512	100.5	13.678
61.5	5.438	81.5	9.710	101.5	13.918
62.5	5.671	82.5	9.907	102.5	14.163
63.5	5.903	83.5	10.104	103.5	14.413

Table II- Females Birth to Attainment of Age 2

Third Percentile Values for Weight-for-Length

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.613	64.5	5.985	84.5	10.071
45.5	1.724	65.5	6.200	85.5	10.270
46.5	1.946	66.5	6.413	86.5	10.469
47.5	2.171	67.5	6.625	87.5	10.670
48.5	2.397	68.5	6.836	88.5	10.871

49.5	2.624	69.5	7.046	89.5	11.074
50.5	2.852	70.5	7.254	90.5	11.278
51.5	3.081	71.5	7.461	91.5	11.484
52.5	3.310	72.5	7.667	92.5	11.691
53.5	3.538	73.5	7.871	93.5	11.901
54.5	3.767	74.5	8.075	94.5	12.112
55.5	3.994	75.5	8.277	95.5	12.326
56.5	4.220	76.5	8.479	96.5	12.541
57.5	4.445	77.5	8.679	97.5	12.760
58.5	4.669	78.5	8.879	98.5	12.981
59.5	4.892	79.5	9.078	99.5	13.205
60.5	5.113	80.5	9.277	100.5	13.431
61.5	5.333	81.5	9.476	101.5	13.661
62.5	5.552	82.5	9.674	102.5	13.895
63.5	5.769	83.5	9.872	103.5	14.132

2. For children age 2 to attainment of age 18, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile value in Table III or Table IV.

Table III - Males Age 2 to Attainment of Age 18

Third Percentile Values for BMI-for-Age

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.1	14.5	10.11 to 11.2	14.3	14.9 to 14.10	16.1

2.2 to 2.4	14.4	11.3 to 11.5	14.4	14.11 to 15.0	16.2
2.5 to 2.7	14.3	11.6 to 11.8	14.5	15.1 to 15.3	16.3
2.8 to 2.11	14.2	11.9 to 11.11	14.6	15.4 to 15.5	16.4
3.0 to 3.2	14.1	12.0 to 12.1	14.7	15.6 to 15.7	16.5
3.3 to 3.6	14.0	12.2 to 12.4	14.8	15.8 to 15.9	16.6
3.7 to 3.11	13.9	12.5 to 12.7	14.9	15.10 to 15.11	16.7
4.0 to 4.5	13.8	12.8 to 12.9	15.0	16.0 to 16.1	16.8
4.6 to 5.0	13.7	12.10 to 13.0	15.1	16.2 to 16.3	16.9
5.1 to 6.0	13.6	13.1 to 13.2	15.2	16.4 to 16.5	17.0
6.1 to 7.6	13.5	13.3 to 13.4	15.3	16.6 to 16.8	17.1
7.7 to 8.6	13.6	13.5 to 13.7	15.4	16.9 to 16.10	17.2
8.7 to 9.1	13.7	13.8 to 13.9	15.5	16.11 to 17.0	17.3
9.2 to 9.6	13.8	13.10 to 13.11	15.6	17.1 to 17.2	17.4
9.7 to 9.11	13.9	14.0 to 14.1	15.7	17.3 to 17.5	17.5
10.0 to 10.3	14.0	14.2 to 14.4	15.8	17.6 to 17.7	17.6
10.4 to 10.7	14.1	14.5 to 14.6	15.9	17.8 to 17.9	17.7
10.8 to 10.10	14.2	14.7 to 14.8	16.0	17.10 to 17.11	17.8

Table IV - Females Age 2 to Attainment of Age 18

Third Percentile Values for BMI-for-Age

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.2	14.1	10.8 to 10.10	14.0	14.3 to 14.5	15.6
2.3 to 2.6	14.0	10.11 to 11.2	14.1	14.6 to 14.7	15.7
2.7 to 2.10	13.9	11.3 to 11.5	14.2	14.8 to 14.9	15.8
2.11 to 3.2	13.8	11.6 to 11.7	14.3	14.10 to 15.0	15.9
3.3 to 3.6	13.7	11.8 to 11.10	14.4	15.1 to 15.2	16.0
3.7 to 3.11	13.6	11.11 to 12.1	14.5	15.3 to 15.5	16.1
4.0 to 4.4	13.5	12.2 to 12.4	14.6	15.6 to 15.7	16.2
4.5 to 4.11	13.4	12.5 to 12.6	14.7	15.8 to 15.10	16.3
5.0 to 5.9	13.3	12.7 to 12.9	14.8	15.11 to 16.0	16.4
5.10 to 7.6	13.2	12.10 to 12.11	14.9	16.1 to 16.3	16.5
7.7 to 8.4	13.3	13.0 to 13.2	15.0	16.4 to 16.6	16.6
8.5 to 8.10	13.4	13.3 to 13.4	15.1	16.7 to 16.9	16.7
8.11 to 9.3	13.5	13.5 to 13.7	15.2	16.10 to 17.0	16.8
9.4 to 9.8	13.6	13.8 to 13.9	15.3	17.1 to 17.3	16.9
9.9 to 10.0	13.7	13.10 to 14.0	15.4	17.4 to 17.7	17.0
10.1 to 10.4	13.8	14.1 to 14.2	15.5	17.8 to 17.11	17.1

10.5 to 10.7	13.9

105.09 Liver transplantation (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.10 Need for supplemental daily enteral feeding via a gastrostomy (see 105.00H) due to any cause, for children who have not attained age 3; after that, evaluate the residual impairment(s).

105.11 Small intestine transplantation (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.12 Pancreas transplantation (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

* * * * *

108.00 SKIN DISORDERS

A. Which skin disorders do we evaluate under these listings? We use these listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (108.07), burns

(108.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (108.09).

B. What are our definitions for the following terms used in this body system?

1. Assistive device(s): An assistive device, for the purposes of these listings, is any device that is used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; or worn, such as a prosthesis or an orthosis.

2. Chronic skin lesions: Chronic skin lesions can have recurrent exacerbations. They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 108.00D2.

3. Contractures: Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 108.00D2.

4. Documented medical need: When we use the term "documented medical need," we mean that there is evidence from your medical source(s) in the medical record that supports your need for an assistive device (see § 416.913 of this chapter). The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device, and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. Fine and gross movements: Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling. Evaluation of fine and gross movements is dependent on your age.

6. Surgical management: For the purposes of these listings, surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

C. What evidence do we need to evaluate your skin disorder?

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations;

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Your history of familial incidence; exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

e. Your ability to function outside of a highly protective environment;

f. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

g. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

h. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. How do we evaluate the severity of skin disorders?

1. General. We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions or contractures, functional limitations caused by your signs and symptoms (including pain) (see 108.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations, how quickly they resolve, and how you function between exacerbations, to determine whether your skin disorder meets or medically equals a listing. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 108.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating your symptoms, see § 416.929 of this chapter.

2. Limitation(s) of physical functioning due to skin disorders.

a. Skin disorders may be due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete age-appropriate activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 108.07B, 108.08, and 108.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see § 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because the characteristics and severity of the disorder itself are sufficient to meet the criteria in 108.07A.

b. The functional criteria require impairment-related physical limitations in using upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements;

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements due to chronic skin lesions or contractures, and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. Frequency of exacerbations due to chronic skin lesions. A skin disorder resulting in chronic skin lesions (see 108.00B2) may have frequent exacerbations severe enough to meet a listing even if each individual skin lesion exacerbation did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations; how quickly they resolve; and how you function in the time between skin lesion exacerbations, to determine whether your skin disorder meets or medically equals a listing.

4. Symptoms (including pain). Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing. We consider your symptoms only when you have a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. See § 416.929 of this chapter.

5. Treatment.

a. General. Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. Despite adherence to prescribed medical treatment for 3 months. Under 108.09, we require that your symptoms persist "despite adherence to prescribed medical treatment for 3 months." This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a physician for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, "sufficient time" means a period of at least three

months. If your treatment has not lasted for at least 3 months, we will follow the rules in 108.00D6a. To evaluate the severity of physical limitations due to your skin disorder(s), we require medically documented evidence of disorder-related physical limitation(s) of functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months. See § 416.909 of this chapter. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics. If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. No record of ongoing treatment.

a. Despite having a skin disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see § 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 108.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 108.00I.

E. How do we evaluate genetic photosensitivity disorders under 108.07? Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. Xeroderma pigmentosum (XP) (108.07A). XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body's ability to repair DNA (deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 108.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 108.00E3).

2. Other genetic photosensitivity disorders (108.07B). The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 108.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 108.00C) and either must result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that result in functional limitations (108.00D), or must result in the inability to function outside of a

highly protective environment. Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 102.00, 111.00, 112.00, or 113.00, as appropriate.

3. What evidence do we need to document that you have XP or another genetic photosensitivity disorder? We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic laboratory test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an acceptable medical source (AMS); or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. Inability to function outside of a highly protective environment means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. How do we evaluate burns under 108.08?

1. Electrical, chemical, or thermal burns frequently affect other body systems; for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological, or mental. We evaluate burns in the same way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 108.00B6), we will evaluate your disorder under the listings in 101.00.

2. We evaluate third-degree burns resulting in contractures (see 108.00B3) that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 108.08. To be disabling, these burns must result in functional limitation(s) (see 108.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. How do we evaluate chronic conditions of the skin or mucous membranes under 108.09? We evaluate skin disorders that result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) under 108.09. These disorders must result in chronic skin lesions or contractures that continue to persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b) and cause functional limitations (see 108.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. How do we evaluate disorders in other body systems that affect the skin? When your disorder(s) in another body system affects the skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that affect the skin include the following:

1. Tuberous sclerosis. The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disability or other mental disorders. We evaluate these features under the listings in 111.00 or 112.00, as appropriate.

2. Malignant tumors of the skin. Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 113.00.

3. Immune system disorders. We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 114.00.

4. Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders. A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 101.00, 102.00, 105.00, or 112.00, as appropriate.

5. Porphyria. We evaluate erythropoietic protoporphyria under the listings in 107.00.

6. Hemangiomas. We evaluate hemangiomas associated with thrombocytopenia and hemorrhage (for example, Kasabach-Merritt syndrome) involving coagulation defects under the listings in 107.00. When hemangiomas impinge on vital structures or interfere with functioning, we evaluate their primary effects under the listings in the appropriate body system.

I. How do we evaluate skin disorders that do not meet one of these listings?

1. These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, we will also consider whether your impairment(s) functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

108.01 Category of Impairments, Skin Disorders

108.02–108.06 [Reserved]

108.07 Genetic photosensitivity disorders, established as described in 108.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 108.00E1).

OR

B. Other genetic photosensitivity disorders (see 108.00E2) with either 1 or 2:

1. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause an inability to function outside of a highly protective environment (see 108.00E4); or

2. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause functional limitations (see 108.00D2) due to limitation(s) from your skin condition, such as pain, as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements; or

b. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic

skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.08 Burns (see 108.00F). Third-degree burns that do not require continuing surgical management, or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and are no longer receiving surgical management, resulting in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause functional limitations (see 108.00D2) due to limitation(s), such as pain, from your skin condition, as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.09 Chronic conditions of the skin or mucous membranes (see 108.00G) resulting in:

A. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3); chronic pain; or other physical limitation(s); that persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b), causing functional limitations (see 108.00D2) due to limitation(s), such as pain, from your skin condition.

AND

B. Impairment-related significant limitation demonstrated by 1, 2, 3, or 4:

1. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements; or

2. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities

due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

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[FR Doc. 2019-15554 Filed: 7/24/2019 8:45 am; Publication Date: 7/25/2019]