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**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**Establishing a TRICARE Low Back Pain and Physical Therapy Demonstration**

**AGENCY:** Department of Defense.

**ACTION:** Notice of demonstration project.

**SUMMARY:** The Director, Defense Health Agency (DHA), has approved the creation of a demonstration to waive cost-sharing for up to three physical therapy (PT) visits for TRICARE beneficiaries with low back pain (LBP). The purpose of the demonstration is to encourage the uptake of PT services for the treatment and management of LBP and to incentivize beneficiaries towards higher-value care and away from lower-value care. This demonstration will operate in 10 states, test whether waiving cost-sharing increases the uptake of PT services among patients with LBP, and measure the impact of LBP on lower-value services such as imaging, opioids, and surgery.

**DATES:** This demonstration project will be effective January 1, 2021, through December 31, 2023, unless terminated earlier by the Director, DHA, or designee.

**FOR FURTHER INFORMATION CONTACT:** Ms. Erica Ferron, Medical Benefits and Reimbursement Section, TRICARE Health Plan, telephone (303) 676-3626.

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**SUPPLEMENTARY INFORMATION:**

**A. Background**

LBP is a common symptom that may be caused by a variety of underlying conditions, including muscle strains, disc degeneration, sciatica, scoliosis, arthritis, and fibromyalgia. Risk factors include age, fitness level, weight, pregnancy, genetics, and occupation. Acute LBP includes pain lasting up to four weeks from onset of symptoms, subacute LBP refers to pain lasting from 4 to 12 weeks, and chronic LBP persists beyond 12 weeks. With rest and self-care, most cases of LBP resolve within six weeks of onset of symptoms, although approximately 20 percent of cases of acute LBP transition to chronic LBP and require additional interventions. Due largely to its high prevalence, LBP results in significant costs. According to a 2016 review by Dieleman et al. published in the Journal of the American Medical Association, low back and neck pain accounted for \$87.6 billion in estimated health care spending in 2013 (the third-highest spending category behind diabetes and ischemic heart disease). Combined direct and indirect costs (e.g., lost wages, inability to work, and decreased productivity) of LBP are estimated to be over \$100 billion per year, according to a 2006 study by JN Katz published in the Journal of Bone and Joint Surgery.

Many national professional medical associations, national expert opinion organizations, and providers have developed treatment guidelines and best practices for treating LBP. These guidelines are intended to maximize patient outcomes and quality of life, as well as increase the value of LBP treatments and diagnostic services. Increasing the value of health care refers to improving patients' quality of care and outcomes, improving patients' access to care, and reducing overall costs of care. In contrast, low-value care refers to interventions that: are not proven to benefit patients; may harm patients; result in unnecessary costs; or waste health care resources. Several types of LBP treatments and diagnostic services are classified as low-value or inappropriate care in the absence of red-flag symptoms, such as imaging services (e.g., x-rays,

computed tomography scans, and magnetic resonance imaging scans) before six weeks from onset of symptoms, surgery for non-specific back pain, opioids as a first- or second-line treatment, and prolonged bedrest. Use of low-value services increases health care costs and patients who receive low-value, inappropriate care for LBP may experience worse outcomes than patients who receive conservative, higher-value measures such as PT. Low-value care is particularly pernicious for LBP patients, as low-value interventions, such as imaging, may lead to further low-value care, such as surgery, with the accompanying potential for negative outcomes or side effects. Likewise, the use of low-value care such as opioids instead of higher-value care, such as PT, may cause the patient to transition from acute pain to chronic pain and may lead to opioid use disorder.

This demonstration was created, in part, due to a TRICARE Health Plan (THP) analysis that found TRICARE beneficiaries who attended PT and occupational therapy (OT) did so at the same rate across beneficiary classes and age groups (i.e., similar proportions attended 1 to 3 visits, 3 to 5 visits, more than 12 visits, etc.); that is, beneficiaries who attended at least one therapy visit tended to attend additional visits at the same rate. However, the percentage of beneficiaries who attended at least one therapy visit varied across beneficiary classes: Active Duty Service members (ADSMs) attended PT or OT at a rate of 65 percent, Active Duty family members (ADFM) at a rate of 42 percent, and non-active duty dependents (NADDs), which includes retirees and all non-ADFM or non-ADSM beneficiaries, at a rate of 38 percent. Notably, NADD beneficiaries have the highest cost-sharing requirements for PT and OT, and the lowest rates of use. Therefore, this demonstration hypothesizes that incentivizing PT services for patients with LBP will result in an increase in the initial and total use of PT services among TRICARE beneficiaries currently subject to cost-sharing. Additionally, the demonstration

hypothesizes that this increase in PT uptake will reduce low-value interventions for LBP, reduce the overall cost of treating LBP, and improve patient outcomes.

## **B. Description of the Demonstration**

This demonstration waives cost-sharing for up to three PT visits for patients with LBP. To be eligible for the demonstration, TRICARE beneficiaries must have a primary diagnosis of LBP, reside and receive PT services in one of the selected demonstration states, and be referred by a TRICARE-authorized provider to receive PT services currently covered by TRICARE.

TRICARE will promulgate a list of ICD-10 diagnosis codes in the implementing instructions.

Additionally, only new PT “episodes” will be eligible for waived cost-sharing (i.e. a patient who is receiving PT services before the beginning of the demonstration may not receive waived cost-sharing for those services once the demonstration starts). Provider reimbursement under this demonstration will follow current TRICARE reimbursement procedures for PT. Likewise, after the third PT visit with waived cost-sharing, beneficiary cost-sharing will follow current cost-sharing methodologies specified in the TRICARE Reimbursement Manual.

There is no limitation on the number of weeks from onset of symptoms to receiving PT services under this demonstration (i.e. PT visits for acute, subacute, or chronic LBP may be eligible for waived cost-sharing), as early access to PT may result in overall lower health care utilization and LBP-related costs within the Military Health System. This supports the demonstration hypothesis that increased uptake of PT visits will reduce the proportion of beneficiaries who transition from acute and subacute LBP to chronic LBP, which may reduce costs while improving patient outcomes.

Provider requirements under this demonstration shall include the following:

- Licensed physical therapists and physical therapist assistants may provide covered physical therapy services to eligible beneficiaries under this demonstration.
- To comply with existing statutory and regulatory requirements for TRICARE, physical therapy must be prescribed by a provider listed at title 32, Code of Federal Regulations, § 199.6(c)(3)(iii)(K)(2).
- Physical therapy services must be performed in a demonstration state to qualify for waived cost-sharing under this demonstration.
- When appropriate, physical therapists should schedule the next appointment immediately to encourage continued use of physical therapy visits.
- Cost-sharing shall be waived for in-network physical therapists.

The following states were selected as demonstration states: Arizona, California, Colorado, Florida, Georgia, Kentucky, North Carolina, Ohio, Tennessee, and Virginia. These states were selected due to their high TRICARE retiree population (the category of beneficiaries with the highest cost-sharing for specialty care and are, therefore, the most likely to be impacted by this demonstration) and to create a comprehensive representation throughout the United States. If this demonstration is successful, the demonstration may be rolled out to the entire TRICARE population. This ensures the demonstration meets ethical standards for experiments.

If a beneficiary moves from a demonstration state to a non-demonstration state, he is no longer eligible for the demonstration. However, if a beneficiary moves from a non-demonstration state to a demonstration state, he becomes eligible for the demonstration, provided he is beginning a new PT treatment (i.e. beneficiaries may not begin a PT treatment in a non-demonstration state, then receive three PT visits without cost-sharing as part of the same treatment plan after moving to a demonstration state). The goal of the demonstration is to determine if incentivizing starting

PT has an impact on patient outcomes and the use of certain interventions; it is not to eliminate beneficiary burden for the entire cost of PT.

This demonstration project will be effective January 1, 2021, through December 31, 2023, unless terminated earlier by the Director, DHA, or designee. DHA may terminate the demonstration early for any reason, including significantly-higher costs than anticipated or a clear failure to achieve any of the hypothesized outcomes in the demonstration states, via subsequent Federal Register notice.

### C. Evaluation

The primary goal of this demonstration is to incentivize the uptake of PT services. The demonstration will also test the below hypotheses using the respective outcome measures listed in Table 1:

TABLE 1 – DEMONSTRATION HYPOTHESES AND OUTCOME MEASURES

Hypothesis*	Outcome Measure(s)
Does waiving cost-sharing for up to three PT visits increase the initial uptake of PT visits among patients with LBP?	Total number of initial PT visits; Proportion of beneficiaries receiving an initial PT visit
Does waiving cost-sharing for up to three PT visits increase the overall number of PT visits among patients with LBP?	Average and median number of PT visits among beneficiaries with LBP
Does incentivizing the use of PT services reduce the number of opioids prescribed to patients with LBP?	Average and median number of opioids prescriptions filled by beneficiaries with LBP
Does incentivizing the use of PT services reduce the amount of imaging services provided to patients with LBP?	Average and median number of imaging services (MRI, CT, X-ray, and Ultrasound) provided to beneficiaries with LBP, stratified across the following time periods and measured from initial diagnosis of LBP: 0-6 weeks; 6-12 weeks; >12 weeks
Does incentivizing the use of PT services reduce the number of back surgeries for patients with LBP?	Proportion of beneficiaries with a diagnosis for LBP receiving back surgeries
Does incentivizing the use of PT services reduce the total cost of care for a LBP episode?	Average and median cost of episode for LBP; Average and median cost of episode for LBP when beneficiary attends at least three PT visits; Average and median cost of episode for LBP when beneficiary attends fewer than three PT visits.
Does improved access to PT services prevent chronic LBP (i.e. do fewer patients transition from acute and subacute pain to chronic pain)?	Proportion of patients receiving services to treat LBP after 12 weeks from initial diagnosis of LBP
Does incentivizing the use of PT services reduce the number of other low value services or other LBP treatments?	Average and median number of number of patients receiving injections, etc.

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\*The above hypotheses are intended to measure the correlational relationship; this evaluation will not make any statements on causation.

The outcome measures listed in Table 1 will be used to determine the success of the demonstration. To estimate the impact of the demonstration on the outcome measures, the evaluation of this demonstration will use a pretest-posttest non-equivalent control group methodology. For each outcome measure, the eligible population in the demonstration states (i.e. the treatment group) will be compared to the eligible population in the non-demonstration states (i.e. the control group) before the demonstration, annually, and at the conclusion of the demonstration. This methodology will allow DHA to estimate the impact of the demonstration (i.e. the treatment effect) by subtracting the difference between the treatment and control groups at baseline from the difference between the groups at the demonstration's conclusion for each outcome measure. Baseline data will consist of one calendar year of data.

In addition to the above outcome measures, this demonstration will include a patient survey to measure reasons a patient begins and ceases PT visits, as well as access to care, quality of care, and overall health status. This information will supplement the outcome measures and will provide important context for the data analysis. For example, if patients cease PT visits because the LBP is resolved, there is evidence that incentivizing PT visits improved patient outcomes. On the other hand, if PT visits cease due to non-compliance or because PT services are not improving patients' symptoms, the demonstration was not successful in improving patient outcomes. The survey will be administered electronically to TRICARE beneficiaries with a primary diagnosis of LBP who receive PT services in demonstration states. The survey questions and collection methodology will go through the Department of Defense licensure process for approval and will require an additional Federal Register notice. The contractor shall provide contact information for participants to DHA, who will administer the survey, collect

survey results, and evaluate survey data. The qualitative and quantitative analyses of survey results may also be used to determine the success of the demonstration. If the survey is not approved, it will not be included in the demonstration or its evaluation.

Dated: June 25, 2020.

**Aaron T. Siegel,**

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*Department of Defense.*

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