MINIMED® 670G SYSTEM HEALTHCARE PROVIDER ADVOCACY TOOL KIT

Medtronic

OVERVIEW FOR HEALTHCARE PROVIDERS WHO WISH TO ENGAGE INSURANCE ORGANIZATIONS THAT CURRENTLY DO NOT COVER THE MINIMED 670G SYSTEM

Medtronic has assembled this tool kit for healthcare providers composed of sample documents and information intended to help assist you in advocating for MiniMed 670G system coverage for your patients.

Please be aware that coverage for the MiniMed 670G system is currently provided by most commercial insurance companies. There are some specific Payers that consider the MiniMed 670G system "Non Covered."

Advocacy can be approached in many ways: communication with a Medical Director at a Payer, proactively pursuing coverage for an individual patient, or requesting an appeal for denied coverage. The intent of this tool kit is to help provide information on processes that are effective and as efficient as possible to obtain coverage.

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FOR CASES WHERE A HEALTHCARE PROVIDER WISHES TO SUBMIT COMMENTARY REGARDING A PAYER'S MEDICAL POLICY:

1. **Obtain contact information for Medical Director from Medtronic representative**
2. **Compose letter and/or email to Medical Director requesting medical policy coverage for the MiniMed 670G system. A clear explanation of the request should include:**
   - A request coverage for the MiniMed 670G system
   - Brief history of your experience and challenges managing patients on basal/bolus insulin regimens
   - Description of the MiniMed 670G system - This toolkit includes a description and photos of the system
   - Any current diabetes- related challenges your patients experience which the MiniMed 670G system could address
   - You may wish to request a direct response from the Medical Director or an opportunity for a live discussion

PROACTIVE REQUESTS FOR INDIVIDUAL PATIENT COVERAGE

DOCUMENTS FROM HEALTHCARE PROVIDER

1. Prescription From Provider

The insurance company will want a copy of your prescription for the MiniMed 670G system.

2. Letter of Medical Necessity

It may be helpful to review the payer's policy in order to compose a narrative Letter of Medical Necessity. The purpose of the letter is to confirm why you (provider) are requesting coverage for the MiniMed 670G system for your patient. This may include:

- A clear explanation of the medical necessity including:
  - Patient demographics
  - Diabetes history
  - Any current diabetes- related challenges your patient is experiencing that may substantiate medical necessity according to the payer's policy

DOCUMENTS PROVIDED BY PATIENT

1. Letter From Patient Requesting Coverage

Submit a letter from the patient requesting coverage approval. The letter should explain:

- Purpose (to request coverage for MiniMed 670G system)
- Personal medical history to demonstrate medical necessity. Provide specific incidences requiring medical intervention which the MiniMed 670G system could likely mitigate
- Request approval for the MiniMed 670G system and ask for the next steps in the process

2. Description of the MiniMed 670G system

The insurance company will want details about the MiniMed 670G system and how it works. This toolkit includes a description and photos of the system. Please print as necessary to provide information your insurance company may require.

REQUESTING AN APPEAL OF DENIED COVERAGE

APPEAL PROCESS

Typically, after your initial request for coverage, the insurance company sends the patient and prescribing provider a letter approving your request or denying it.

However, pursuing coverage for new technology often requires an appeal. If a denial is received, review the letter for details on how to submit an appeal. It may be necessary to produce additional information to facilitate the appeal process.

Appeal Letter

Submit a letter from healthcare provider requesting an appeal. The letter should include:

- Your purpose (to appeal your coverage request for the MiniMed 670G system)
- Restatement of the reason the insurance company denied the initial request and documented reasons why the company should re-evaluate
- Any supplemental information your insurance company has requested
- Repeat your request for approval for the MiniMed 670G system

Important Safety Information: MiniMed® 670G System

The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G system includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2.4 blood glucose meter and not on values provided by the Guardian Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2.4 blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an alternative site (palm) or from a control solution test. Do not calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the "Always" send mode. **WARNING: Medtronic performed an evaluation of the MiniMed 670G system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely**. Only use rapid acting U100 insulin with this system. Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed 670G system has not been studied in pregnant women. For complete details, including product and important safety information concerning the system and its components, please consult http://www.medtronicdiabetes.com/important-safety-information#minimed-670g and the appropriate user guide at http://www.medtronicdiabetes.com/download-library.