Pharmacy Policy

Iprivask®

Policy Number: 9.028
Version Number: 9.0
Version Effective Date: 05/02/2017

Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of Iprivask® when appropriate criteria are met.

Description of Item or Service

Iprivask® (desirudin) is a direct thrombin inhibitor (DTI) indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients undergoing elective hip replacement surgery. Desirudin exerts its anticoagulant activity by selectively inhibiting both free circulating and clot-bound thrombin thereby prolonging plasma clotting time. In clinical studies, desirudin was found to be superior to both heparin and enoxaparin in head-to-head clinical trials in preventing proximal DVT and major venous thromboembolism (VTE) events after elective hip replacement surgery. The rate of hemorrhagic events was comparable in patients receiving desirudin, enoxaparin and heparin.

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Iprivask® carries a **Black Box Warning** related to the potential risk for *spinal/epidural hematomas*. Patients anticoagulated or scheduled to be anticoagulated with selective inhibitors of thrombin may be at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis when neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is utilized.

The most recent guidelines from the American College of Chest Physicians (ACCP) recommends either low molecular weight heparin (LMWH), fondaparinux (factor Xa inhibitor) or an adjusted dose vitamin K antagonist (VKA) for the prevention of VTE in patients undergoing elective total hip replacement. Desirudin represents the first subcutaneous DTI approved in the United States for DVT prophylaxis in elective hip replacement surgery. Other intravenous direct thrombin inhibitors are mostly used as anticoagulants in patients with a history of heparin induced thrombocytopenia (HIT). Its place in therapy has not yet been established.

**Policy**

The Plan may authorize coverage of Iprivask® for members meeting the following criteria:

**Prior Authorization** – (Duration of approval – Maximum of 30 days)

A prior authorization request will be required for all prescriptions for Iprivask®. These requests will be approved when the following criteria are met:

Documentation of the following:

1. Deep vein thrombosis (DVT) prophylaxis is required for elective total hip replacement surgery; **AND**

2. A contraindication or intolerance to treatment with all of the following agents:
   i. Low molecular weight heparin (LMWH)
   ii. Factor Xa inhibitors
   iii. Vitamin K antagonists; **OR**
      the member has a history of thrombocytopenia or heparin-induced thrombocytopenia.

**Limitations**

The Plan will not approve coverage of Iprivask® in the following instances:

- When the above criteria are not met.

**Clinical Background Information and References**


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**Policy Revisions History**

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Next Review Date

01/11/2017

Other Applicable Policies

9.002 MandatoryGeneric Substitution Program

Reference to Applicable Laws and Regulations, If Any

N/A

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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