I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Pramlintide acetate (Symlin) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Pramlintide acetate (Symlin).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V.  PROCEDURE

Pramlintide acetate is indicated for the treatment of members with type 1 diabetes as an adjunct treatment to mealtime insulin and have failed to achieve desired glucose control despite optimal insulin therapy.

Pramlintide acetate is also indicated for the treatment of members with type 2 diabetes who use mealtime insulin therapy and have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.

Criteria:

1. The criteria for automatic coverage of pramlintide acetate are as follows:
   a. Claim history for insulin in the 3 months prior to filling pramlintide and;
   b. Prescription is written by an Endocrinologist
2. For members without prior claim history of pramlintide, a medical necessity review will completed, and the following criteria must be met for approval:
   a. Members must have a diagnosis of type 1 or 2 diabetes mellitus and currently on mealtime insulin.
   b. Member must have a HbA1C level less than or equal to 9%.
   c. An endocrinologist must prescribe and supportive services of a diabetes educator must be available to the member.
   d. Proper patient selection is crucial to verify the safe and effective use of this medication and therefore the prescribing physician must verify that member is compliant with self-monitoring of blood glucose and aware of hypoglycemia risk.
   e. Pramlintide will have quantity limits due to potential for dose confusion and user error. Quantity limits will be 4 vials for a 30 day supply which will allow for the maximum daily dose of 120 mcg three times daily.

Pramlintide is supplied in a 5 mL vial containing 0.6mg/mL.

<table>
<thead>
<tr>
<th>Dosage Prescribed (micrograms)</th>
<th>Increment Using U-100 Syringe (units)</th>
<th>Volume (cc or mL)</th>
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<tbody>
<tr>
<td>15</td>
<td>2.5</td>
<td>0.025</td>
</tr>
<tr>
<td>30</td>
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</tr>
<tr>
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<td>7.5</td>
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<tr>
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</tr>
<tr>
<td>120</td>
<td>20.0</td>
<td>0.200</td>
</tr>
</tbody>
</table>

Limitations:
If a member does not meet the above approval criteria, the request will be sent to a UPMC Health Plan Medical Director for review.

VI.  BIBLIOGRAPHY


Proprietary and Confidential Information of UPMC Health Plan