## Drug Therapy Guidelines

### Applicable

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th></th>
<th>Effective: 6/21/17</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 6/18</td>
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<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
<td>Date of Origin: 4/17</td>
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<td>Pharmacy- Formulary 3/Exclusive</td>
<td>x</td>
<td>Review Dates: 3/17, 3/17</td>
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<td>Pharmacy- Formulary 4/AON</td>
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### I. Medication Description

Telotristat, the active metabolite of telotristat ethyl, is an inhibitor of tryptophan hydroxylase, which mediates the rate limiting step in serotonin biosynthesis. The *in vitro* inhibitory potency of telotristat towards tryptophan hydroxylase is 29 times higher than that of telotristat ethyl. Serotonin plays a role in mediating secretion, motility, inflammation, and sensation of the gastrointestinal tract, and is over-produced in patients with carcinoid syndrome. Through inhibition of tryptophan hydroxylase, telotristat and telotristat ethyl reduce the production of peripheral serotonin, and the frequency of carcinoid syndrome diarrhea.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for all requests.

### III. Policy

Coverage of Xermelo is available when the following criteria have been met:
- Member is at least 18 years of age **AND**
- Member has carcinoid syndrome diarrhea that is uncontrolled despite maximum dosing with a somatostatin analog **AND**
- Xermelo is used in combination with a somatostatin analog

### IV. Quantity Limitations

One monthly case (84 tablets) covered per each month.

### V. Coverage Duration

Coverage may be provided for up to 12 months and may be renewed.

### VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following:
- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Xermelo is dispensed in a monthly case for a total of 28 days of therapy
- Each monthly case contains four weekly boxes
- Each weekly box contains seven daily dose packs (day pack)
- Each child-resistant day pack contains three 250mg tablets

VIII. Summary of Policy Changes

- 4/28/17: new policy
- 6/21/17: no policy changes

IX. References

11. Octreotide acetate injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi, USA; May 2014.
| Drug Therapy Guidelines | Xermelo™ (telotristat ethyl) | Last Review Date: 5/2017 |


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*