Potassium Binders

Description

Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)

Background
Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer for oral suspension) are used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. The kidneys remove potassium from the blood to maintain a proper balance of potassium in the body. But when the kidneys are not able to remove enough potassium from the blood, the level of potassium can get too high. Hyperkalemia typically occurs in patients with acute or chronic kidney disease or heart failure, particularly in those who are taking drugs that inhibit the renin-angiotensin-aldosterone system (RAAS), which regulates blood pressure and fluid balance in the body. Lokelma and Veltassa work by binding potassium in the gastrointestinal tract, decreasing its absorption. Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action (1-2).

Regulatory Status
FDA-approved indication: Lokelma and Veltassa are potassium binders indicated for the treatment of hyperkalemia (1-2).

Limitation of Use:
Lokelma and Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of the delayed onset of action (1).
Lokelma and Veltassa could decrease the absorption of other medications and reduce their effectiveness. Administer other oral medications at least 3 hours before or 3 hours after Veltassa and 2 hours before or 2 hours after Lokelma (1-2).

The recommended starting dose of Veltassa is 8.4 grams once daily. Monitor serum potassium and adjust the dose of Veltassa based on the serum potassium level and the desired target range. The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily. The dose can be up-titrated based on serum potassium level at 1-week or longer intervals, in increments of 8.4 grams (1).

The recommended starting dose of Lokelma is 10 grams (orally as a suspension in water) administered three times a day for up to 48 hours. For maintenance treatment, recommend dose is 10 grams once daily. Adjust dose at one-week intervals as needed (by 5 grams daily) to obtain desired serum potassium target. Maximum dosage of Lokelma is 15 grams daily (2).

Avoid use of Lokelma and Veltassa in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Lokelma and Veltassa have not been studied in patients with these conditions and may be ineffective and may worsen gastrointestinal conditions (1-2).

Safety and efficacy of Lokelma and Veltassa in pediatric patients have not been established (1-2).

Related policies

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lokelma and Veltassa may be considered medically necessary in patients that are 18 years and older for the treatment of hyperkalemia and when the conditions indicated below are met.

Lokelma and Veltassa are considered investigational in patients less than 18 years of age and for all other indications.
Prior-Approval Requirements

Age  18 years of age or older

Diagnosis

Patient must have the following:

Hyperkalemia

AND ALL of the following:
1. Physician agrees to adjust the dose based on the serum potassium level
2. NOT using as emergency treatment for life-threatening hyperkalemia
3. Patient is NOT taking a drug that can cause hyperkalemia (such as ACE inhibitor, ARB, aldosterone antagonist, or potassium-sparing diuretic) OR if there is no therapeutic alternative to these medications, patient is using the lowest effective dose
4. Inadequate treatment response, intolerance, or contraindication to a loop or thiazide diuretic
5. Patient is on a low potassium diet (2-3 grams per day)
6. NO dual therapy with another potassium binder

Prior – Approval Renewal Requirements

Age  18 years of age or older

Diagnosis

Patient must have the following:

Hyperkalemia

AND ALL of the following:
1. Physician agrees to adjust the dose based on the serum potassium level
2. NOT using as emergency treatment for life-threatening hyperkalemia
3. Patient is not taking a drug that can cause hyperkalemia (such as ACE inhibitor, ARB, aldosterone antagonist, or potassium-sparing diuretic) OR if there is no
therapeutic alternative to these medications, patient is using the lowest effective dose
4. Patient is on a low potassium diet (2-3 grams per day)
5. NO dual therapy with another potassium binder

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior – Approval Limit**

**Quantity**

**Lokelma**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>5 gm packet</td>
<td>270 packets per 90 days</td>
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<tr>
<td>10 gm packet</td>
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**Veltassa**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>8.4 gm packet</td>
<td>270 packets per 90 days OR</td>
</tr>
<tr>
<td>16.8 gm packet</td>
<td>90 packets per 90 days OR</td>
</tr>
<tr>
<td>25.2 gm packet</td>
<td>90 packets per 90 days</td>
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*Maximum daily limit of any combination of Veltassa: 25.2 gm

**Duration**

12 months

**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**

Lokelma and Veltassa is used to treat high levels of potassium in blood (hyperkalemia). Monitor serum potassium and adjust the dose of Lokelma and Veltassa based on the serum potassium
level and the desired target range. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of the delayed onset of action. Lokelma and Veltassa may affect other medicines taken by mouth if they are taken too close together. Safety and efficacy in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Lokelma and Veltassa while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>February 2016</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2018</td>
<td>Change in policy name from “Veltassa” to “Potassium Binders” and initiation duration from 6 months to 12 months</td>
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<tr>
<td></td>
<td>Addition of Lokelma to PA</td>
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<tr>
<td></td>
<td>Addition of no dual therapy to initiation and renewal criteria</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review and reference update. Addition of requirements per SME: patient is not taking a drug that can cause hyperkalemia; inadequate response, intolerance, or contraindication to a loop or thiazide diuretic; patient is on a low potassium diet; and removal of Kayexalate trial requirement</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.