Formulary Exception, Medical Necessity, and Appeal Letters

A guide for composing VELTASSA coverage authorization requests and appeals

This guide to Medical Necessity, Formulary Exceptions, and Appeal Letters provides sample letters and considerations prescribers can use when composing coverage authorization requests and appeals. The samples provided can be customized to a patient's medical history and clinical needs.

Please note that some plans have specific forms that must be used to document a coverage request. You are encouraged to check directly with the payor on specific coverage conditions.

Sample Letter Templates Available Here

INDICATION

VELTASSA is indicated for the treatment of hyperkalemia in adults and pediatric patients ages 12 years and older.

Limitation of Use: VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Please see additional Important Safety Information on the last page.
Please see the accompanying full Prescribing Information, or click here.

Veltassa® (patiromer) for oral suspension

Tips for Composing Coverage Authorization Requests and Appeal Letters

1. Include all necessary patient (full name, date of birth, insurance information) and prescriber (specialty, phone number, NPI #) information. Also be sure to check with the insurance company for any additional specific requirements.

2. Discuss the patient's history and current conditions, prior treatments, rationale for discontinuation of prior therapies, and relevant laboratory results; be sure to attach supporting documentation and the VELTASSA prescribing information.

3. Detail your clinical rationale for why VELTASSA is recommended, including information from the prescribing information, clinical trial data, peer-reviewed literature, and/or guideline publications that are specific and relevant to the patient.

Unique Attributes of VELTASSA

Sodium-free Exchange
For patients at risk of edema or worsening heart failure, VELTASSA utilizes sodium-free exchange and does not contain a warning for fluid-related concerns.

Once-daily Dosing
Once-daily dosing simplifies potential drug separation issues in patients with high treatment burden.

Pediatric Indication
VELTASSA is the only potassium binder with an indication for pediatric patients aged 12 to less than 18.

Preparation Options
VELTASSA can be prepared in vehicles other than water, including other beverages and soft foods.

Guideline-Directed Medical Therapies

The 2024 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease recommend the use of potassium binders in patients on ACEi or ARB with hyperkalemia before reducing or stopping the ACEi or ARB.[1]

The 2013 American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) guidelines recommend restriction of sodium to 1,500–3,000 mg/day.[2]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components.

Sample Formulary Exception Letter

[Prescriber/Practice Letterhead]

[Formulary director name]
[Health plan/insurance company]
[Address]
[City, State, Zip]

Patient Name: **[Patient Name]**
Patient DOB: **[Patient Date of Birth]**
Policy Number: **[Plan Identification Number]**

[Date]
Subject: Formulary Exception Requested for VELTASSA® (patiromer) for Oral Suspension

Dear **[Formulary director's name]**:

I am writing this letter on behalf of my patient, **[name of patient]**, who is currently a member of **[health plan name]**. I am requesting a formulary exception for **[his/her/their]** prescription of VELTASSA. Currently, VELTASSA is not listed on **[health plan name]'s** formulary.

This letter serves to request that VELTASSA be available to **[name of patient]** as a preferred drug and that any applicable NDC blocks be removed.

Summary of Patient's Medical History and Diagnosis

[Name of patient] is a **[age]**-year-old **[gender]** who was diagnosed with hyperkalemia (ICD-10 E87.5) on **[mm-dd-yyyy]**. **[Name of patient]** has been in my care since **[date]**.

[Provide a brief discussion of patient's history and current condition, laboratory results, previous treatments, reason for discontinuation of past treatments, unresolved symptoms].

Rationale for Treatment with VELTASSA

VELTASSA **[was/will be]** prescribed to **[patient name]** for the treatment of hyperkalemia due to **[cause of hyperkalemia]**. In my medical opinion, **[covered or tiered therapy]** is not an appropriate option for my patient.

[Provide a brief discussion of the factors leading you to recommend the use of VELTASSA vs other treatment options. You may wish to include specific unique attributes of VELTASSA that are applicable to your patient's medical needs.]

Disease State Information

[If applicable, include relevant Guideline Directed Medical Therapies or other references to support the use of your prescribed therapy]

In summary, treatment with VELTASSA is medically necessary for this patient, as outlined above, based on **[his/her/their]** medical history, diagnosis of hyperkalemia, and other enclosed supporting documentation. Because of this, I expect that your coverage for the cost of VELTASSA would be appropriate, and I am confident you will agree. Please contact me at **[prescriber's telephone number]** for a peer-to-peer review or if I can answer any pending questions.

Thank you in advance for your immediate attention to this request.

Sincerely,
[Prescriber's Signature]
[Prescriber's Name & Credentials]
[Prescriber's NPI #]

Enclosures:
[Package insert for VELTASSA]
[Copy of patient medical records]
[Other supporting documentation or publications]

Disclaimer: Sample letters are provided for your reference only. Use of these sample letters and example supporting information does not guarantee an insurance company will cover VELTASSA. The information provided is not intended to replace or influence a prescriber's professional medical judgment.

WARNINGS AND PRECAUTIONS

Worsening of Gastrointestinal Motility: Avoid use of VELTASSA in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because VELTASSA may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in clinical studies.

Sample Letter of Medical Necessity

[Prescriber/Practice Letterhead]

[Medical director name]
[Health plan/insurance company]
[Address]
[City, State, Zip]

Patient Name: **[Patient Name]**
Patient DOB: **[Patient Date of Birth]**
Policy Number: **[Plan Identification Number]**
Claim Number: **[Claim Number]**

[Date]
Subject: Supporting Coverage of VELTASSA® (patiromer) For Oral Suspension

Dear **[Medical director's name]**:

I am writing this letter to document that my patient, **[name of patient]**, has been diagnosed with hyperkalemia and that treatment with VELTASSA is medically necessary for **[him/her/them]**, as prescribed.

This letter serves to document my patient's medical history and diagnosis, summarize my treatment rationale, as well as provide a copy of the Prescribing Information for VELTASSA **[and additional supporting documentation]**.

Summary of Patient's Medical History and Diagnosis

[Name of patient] is a **[age]**-year-old **[gender]** who was diagnosed with hyperkalemia (ICD-10 E87.5) on **[mm-dd-yyyy]**. **[Name of patient]** has been in my care since **[date]**.

[Provide a brief discussion of patient's history and current condition, laboratory results, previous treatments, reason for discontinuation of past treatments, unresolved symptoms].

Rationale for Treatment with VELTASSA

VELTASSA **[was/will be]** prescribed to **[patient name]** for the treatment of hyperkalemia due to **[cause of hyperkalemia]**. In my medical opinion, **[covered or tiered therapy]** is not an appropriate option for my patient.

[Provide a brief discussion of the factors leading you to recommend the use of VELTASSA vs other treatment options. You may wish to include specific unique attributes of VELTASSA that are applicable to your patient's medical needs.]

Disease State Information

[If applicable, include relevant Guideline Directed Medical Therapies or other references to support the use of your prescribed therapy]

In summary, treatment with VELTASSA is medically necessary for this patient, as outlined above, based on **[his/her/their]** medical history, diagnosis of hyperkalemia, and other enclosed supporting documentation. Because of this, I expect that your coverage for the cost of VELTASSA would be appropriate, and I am confident you will agree. Please contact me at **[prescriber's telephone number]** if I can provide additional information about this case.

Thank you in advance for your immediate attention to this request.

Sincerely,
[Prescriber's Signature]
[Prescriber's Name & Credentials]
[Prescriber's NPI #]

Enclosures:
[Package insert for VELTASSA]
[Copy of patient medical records]
[Other supporting documentation or publications]

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WARNINGS AND PRECAUTIONS (CON'T)

Hypomagnesemia: VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of adult patients treated with VELTASSA. Approximately 9% of adult patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels.

Sample Letter of Appeal

[Prescriber/Practice Letterhead]

[Medical director name]
[Health plan/insurance company]
[Address]
[City, State, Zip]

Patient Name: **[Patient Name]**
Patient DOB: **[Patient Date of Birth]**
Policy Number: **[Plan Identification Number]**
Claim Number: **[PA/Formulary Exception Number]**

[Date]
Subject: Appeal for Coverage of VELTASSA® (patiromer) for Oral Suspension

Dear **[Medical director's name]**:

I am writing this letter on behalf of my patient, **[name of patient]**, to request an Appeal of a denied **[Prior Authorization/Formulary Exception]** for **[his/her/their]** prescription of VELTASSA. According to the denial letter, **[name of insurer/Medicare contractor]** denied this **[Prior Authorization/Formulary Exception]** because **[reason for denial listed in the letter]**.

This letter serves to request a formal Appeal of the denied **[Prior Authorization/Formulary Exception]** for **[name of patient]**, with the policy number listed above.

Summary of Patient's Medical History and Diagnosis

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Rationale for Treatment with VELTASSA

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[Provide a brief discussion of the factors leading you to recommend the use of VELTASSA vs other treatment options. You may wish to include specific unique attributes of VELTASSA that are applicable to your patient's medical needs.]

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Thank you in advance for your immediate attention to this request.

Sincerely,
[Prescriber's Signature]
[Prescriber's Name & Credentials]
[Prescriber's NPI #]

Enclosures:
[Package insert for VELTASSA]
[Copy of patient medical records]
[Other supporting documentation or publications]
[Copy of denial letter]

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MOST COMMON ADVERSE EVENTS

The most common adverse reactions (incidence ≥ 2%) in adult patients treated with VELTASSA were constipation (7.2%), hypomagnesemia (5.3%), diarrhea (4.8%), nausea (2.3%), abdominal discomfort (2.0%) and flatulence (2.0%). Mild to moderate hypersensitivity reactions were reported in 0.3% of adult patients treated with VELTASSA and included edema of the lips. The safety profile of VELTASSA in a study of 14 pediatric patients ages 12 to 17 years was generally similar to that observed in adult patients.

Visit VELTASSA.com/hcp/access-savings for downloadable template letters and additional information.

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Hypomagnesemia: VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of adult patients treated with VELTASSA. Approximately 9% of adult patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels.

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Please click here to see the full prescribing information, or see attached PI.

References: 1. Kidney Disease: Improving Global Outcomes (KDIGO). KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney Int Suppl. 2024;105(Suppl 4S):S117-S314. **2.** Yancy CW, Jessup M, Bozkurt B, et al; in collaboration with American College of Chest Physicians, Heart Rhythm Society, and International Society for Heart and Lung Transplantation. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;62(16):e147–e239. doi:10.1016/j.jacc.2013.05.019

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