

SENTARA COMMUNITY PLAN (MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If the information provided is not complete, correct, or legible, the authorization process can be delayed.

Drug Requested: Aqvesme™ (mitapivat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: 100 mg orally twice daily

Quantity Limits: 4 blister wallets containing 14 tablets each (56 total tablets, 28-day supply)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- Member is 18 years of age or older
- Requesting provider is a hematologist, has been in consultation with one, or a specialist in treating patients with alpha-, or beta-thalassemia

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- ❑ Member does **NOT** have hepatobiliary conditions, including but not limited to: Liver disease with histopathological evidence of cirrhosis or severe fibrosis, clinically symptomatic cholelithiasis or cholecystitis, drug-induced cholestatic hepatitis, Aspartate aminotransferase $>2.5 \times$ upper limit of normal (unless due to hemolysis and hepatic iron deposition) and alanine aminotransferase $>2.5 \times$ upper limit of normal (unless due to hepatic iron deposition) (**submit lab documentation**)
- ❑ Prescribed medication will **NOT** be used concurrently with Pyrukynd[®] (mitapivat) or Reblozyl[®] (luspatercept-aamt)
- ❑ Member does **NOT** have a history of prior gene therapy (i.e., Casgevy[®] (exagamglogene autotemcel), Zynteglo[®] (betibeglogene autotemcel))
- ❑ Member must meet **ONE** of the following:
 - ❑ Member has a diagnosis of α -thalassemia meeting **ALL** the following (**please submit medical history and chart notes containing hematological findings, electrophoresis analysis, and/or molecular analysis where available**):
 - ❑ Baseline hemoglobin level of ≤ 10.0 g/dL, **OR** hemoglobin level >10.0 g/dL if the member is transfusion-dependent [laboratory documentation required]
 - ❑ For members with transfusion-dependent thalassemia, the member has received at least 6 red blood cell units transfused within the preceding 24 weeks (**submit most recent chart notes/procedural notes/therapy orders detailing current and past transfusion requirements**)
Please Provide Pretreatment Transfusion Requirements: _____ units
 - ❑ Member does **NOT** have a documented history of homozygous or heterozygous Sickle Hemoglobin (HbS) or Hemoglobin C (HbC)

OR

- ❑ Member has a diagnosis of β -thalassemia including β^+ , β^0 , hemoglobin E/ β -thalassemia, or non-deletional Hb H meeting **ALL** the following (**please submit medical history and chart notes containing hematological findings, electrophoresis analysis, and/or molecular analysis where available**):
 - ❑ Baseline hemoglobin level of ≤ 10.0 g/dL, **OR** hemoglobin level >10.0 g/dL if the member is transfusion-dependent (**submit lab documentation**)
 - ❑ For members with transfusion-dependent thalassemia, the member has received at least 6 red blood cell units transfused within the preceding 24 weeks (**submit most recent chart notes/procedural notes/therapy orders detailing current and past transfusion requirements**)
Please Provide Pretreatment Transfusion Requirements: _____ units
- ❑ Member does **NOT** have a documented history of homozygous or heterozygous Sickle Hemoglobin (HbS) or Hemoglobin C (HbC)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the diagnosis and therapy preclusions listed above

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- ❑ Provider has continued to monitor liver function (ALT, AST, alkaline phosphatase, and total bilirubin with fractionation), and acknowledges the member does **NOT** have liver cirrhosis or hepatic injury **(submit lab documentation)**
- ❑ Member has experienced a clinically meaningful benefit meeting **ONE** of the following:
 - ❑ For members with transfusion-dependent thalassemia, the member has **NOT** experienced an increase in transfusion requirements from pretreatment baseline, or the last authorization review **(submit most recent chart notes/procedural notes/therapy orders detailing current and past transfusion requirements)**
Please Provide Current Transfusion Requirements: _____ units
 - ❑ For members with non-transfusion dependent thalassemia, there has been a stabilization or improvement in the hemoglobin level **(submit lab documentation)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.