Medical Necessity Guidelines: 
Adakveo® (crizanlizumab-tmca)

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.  

<table>
<thead>
<tr>
<th>Applies to:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial Products</strong></td>
</tr>
<tr>
<td>☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988</td>
</tr>
<tr>
<td>☒ Tufts Health Plan Commercial products; Fax 617-673-0988</td>
</tr>
<tr>
<td>CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</td>
</tr>
<tr>
<td><strong>Public Plans Products</strong></td>
</tr>
<tr>
<td>☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988</td>
</tr>
<tr>
<td>☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988</td>
</tr>
<tr>
<td>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988</td>
</tr>
<tr>
<td>☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956</td>
</tr>
<tr>
<td>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</td>
</tr>
<tr>
<td><strong>Senior Products</strong></td>
</tr>
<tr>
<td>☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956</td>
</tr>
<tr>
<td>☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956</td>
</tr>
<tr>
<td>☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956</td>
</tr>
<tr>
<td>☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956</td>
</tr>
</tbody>
</table>

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:
- Adakveo (crizanlizumab-tmca) is a selectin blocker indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease

Clinical Guideline Coverage Criteria

Initial Authorization Criteria:
The Plan may cover Adakveo (crizanlizumab-tmca) for Members when all the following clinical criteria are met:
1. Documented diagnosis of sickle cell disease  
   AND
2. Member is at least 16 years of age  
   AND
3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist  
   AND
4. Documentation the Member experienced at least one sickle cell-related vasoocclusive crises within the previous 12 months  
   AND
5. Documentation of one of the following:
   a. Member is currently receiving hydroxyurea therapy
   b. Member has a previous treatment failure, intolerance, or contraindication to hydroxyurea therapy

Reauthorization Criteria:
1. Documented diagnosis of sickle cell disease
   AND
2. The Member is at least 16 years of age
   AND
3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist
   AND
4. Documentation of one of the following:
   a. Member is currently receiving hydroxyurea therapy
   b. Member has a previous treatment failure, intolerance, or contraindication to hydroxyurea therapy
   AND
5. Documentation the Member has experienced a therapeutic response as defined by at least one of the following:
   a. Reduction in sickle cell-related vasoocclusive crises from pretreatment baseline
   b. Decrease in severity of sickle cell-related vasoocclusive crises from pretreatment baseline

Limitations
- Initial approval by the plan will be limited to 12 months. Reauthorizations will be provided in 12-month intervals.
- Members new to the plan stable on Adakveo (crizanlizumab-tmca) should be reviewed against the Reauthorization Criteria.

Codes
The following code(s) require prior authorization:

Table 1: HCPCS Codes
<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0791</td>
<td>Injection, crizanlizumab-tmca, 5 mg</td>
</tr>
</tbody>
</table>

References:

Approval And Revision History
September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.