Clinical Policy: Sickle Cell Disease Observation
Reference Number: CP.MP.88
Last Review Date: 07/18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Medical necessity criteria for sickle cell disease observation status.

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that the observation level of care is medically necessary for members who do not meet inpatient status criteria per a nationally recognized clinical decision making support tool, but who meet the following criteria:
   A. Episode Day 1:
      1. Intractable pain despite routine home therapy (including narcotics, heat, massage, rest, etc.), and
      2. Suboptimal improvement in pain following at least 4-6 hours of intravenous (IV) or intramuscular (IM) analgesic treatment in the emergency department (ED) or an alternate outpatient setting, and
      3. Requires continued IV or IM analgesic treatment and/or IV fluids for pain management.

   B. Episode Day 2:
      Any days beyond episode day one in observation that do not meet inpatient criteria must be reviewed by a physician. Lack of scheduled or continuous dosing of analgesics and adequate IV fluids indicate suboptimal treatment of a vaso-occlusive pain crisis.

   C. Discharge Criteria:
      1. Pain is controlled with oral analgesics; and
      2. Adequate oral intake; and
      3. Patient educated on comprehensive pain plan tailored to his/her individual needs.

Background
Episodes of acute pain are the most common type of vaso-occlusive event in sickle cell disease (SCD). An acute pain episode is the most common reason for individuals with SCD to seek medical attention. Pain can be triggered by things such as stress, weather conditions, dehydration, infection, menses, and alcohol consumption, but most episodes have no identified cause. The pain most commonly affects the back, chest, extremities, and abdomen, but can occur in any area of the body. Pain ranges from mild to excruciating and can be accompanied by objective clinical signs such as fever, swelling, tenderness, tachypnea, hypertension, nausea and vomiting.

Every individual with SCD should have an established pain plan tailored to his or her needs. These plans should outline how to appropriately manage their pain at home and include pre-
defined thresholds for the use of opioids and when to contact their health care providers. When adequate relief is not achievable in the home, patients often present to the ED for treatment.

When patients present to the ED with acute pain, other causes of the pain should be excluded, particularly infection, prior to developing a treatment strategy. An acute pain crisis is best managed with optimal hydration and aggressive pain relief. IV fluid resuscitation and analgesics can be effectively administered in the observation setting when efforts at treating the pain episode at home are unsuccessful and the pain is not severe enough to warrant an inpatient admission.

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy developed</td>
<td>09/13</td>
<td></td>
</tr>
<tr>
<td>References reviewed and updated</td>
<td>09/14</td>
<td>09/14</td>
</tr>
<tr>
<td>Changed language in II.A from referred to Medical Director to reviewed by a physician</td>
<td>09/15</td>
<td>09/15</td>
</tr>
<tr>
<td>Converted into new template</td>
<td></td>
<td></td>
</tr>
<tr>
<td>References reviewed and updated. Clarified in I. that the member does not meet inpatient status “per a nationally recognized clinical decision making support tool.”</td>
<td>09/16</td>
<td>09/16</td>
</tr>
<tr>
<td>References reviewed and updated.</td>
<td>09/17</td>
<td>09/17</td>
</tr>
<tr>
<td>References reviewed and updated.</td>
<td>07/18</td>
<td>07/18</td>
</tr>
</tbody>
</table>

References
2. DeBaun MR, Vichinsky EP. Acute pain management in adults with sickle cell disease. In: UpToDate, Mahoney DH, Schrier SL (Ed), UpToDate, Waltham, MA. Accessed 09/05/17.
3. Field JJ, Vichinsky EP, DeBaun MR. Overview of the management and prognosis of sickle cell disease. In: UpToDate, Schrier SL, Mahoney DH (Ed), UpToDate, Waltham, MA. Accessed 07/05/18.
4. McKesson Corporation InterQual® criteria
5. Steinberg MH. Vasoocclusion in sickle cell disease. In: UpToDate, Schrier SL (Ed), UpToDate, Waltham, MA. Accessed 09/05/17.
**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.
Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.