Crovalimab (Piasky) – PA Criteria

HCPC: J1307

Crovalimab (Piasky) is a C5 complement inhibitor indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Therapy is requested by or in consultation with a hematologist, oncologist or immunologist
  - Individual has a documented diagnosis of PNH confirmed by flow cytometry
  - Individual is transfusion dependent (requiring ≥ 4 transfusions in past 12 months) as a result of PNH and documentation is provided indicating the frequency of transfusions
  - Documentation is provided indicating baseline values for hemoglobin and lactate dehydrogenase (LDH)
  - Documentation of one or more of the following indicating systemic complications: abdominal pain, dysphagia/odynophagia, shortness of breath, chest pain/pressure, hemoglobinuria, end organ damage, thrombosis, etc.
  - Therapy is not prescribed in combination with other biologics for PNH (Ex. eculizumab, ravulizumab, pegcetacoplan, iptacopan, etc.)
  - Individual is ≥13 years of age
  - Individual is ≥40kg
  - Approval duration: 6 months
- **Continuation of Therapy (must meet all):**
  - Therapy is not prescribed in combination with other biologics for the requested indication
  - Individual has had a positive clinical response as indicated by **one or more** of the following:
    - Stabilization or decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in hemoglobin level from pretreatment baseline
    - Decrease in packed RBC transfusion requirement from pretreatment baseline
  - Approval duration: 1 year