November 1, 2020

MEDICAL REVIEW GUIDELINES EFFECTIVE FEBRUARY 1, 2021

AVSOLA™ (INFLIXIMAB-AXXQ), INFLECTRA® (INFLIXIMAB-DYYB) AND RENFLEXIS® (INFLIXIMAB-ABDA)

Avsola™ (infliximab-axxq), Inflectra® (infliximab-dyyb) and Renflexis® (infliximab-abda) are the preferred infliximab products. Community will provide coverage for Avsola™ (infliximab-axxq), Inflectra® (infliximab-dyyb) and Renflexis® (infliximab-abda) for Members meeting the Diagnosis-Specific Criteria.

Remicade® (infliximab) is non-preferred, and is subject to both Preferred Product Criteria and Diagnosis-Specific Criteria. Treatment with Remicade® (infliximab) is medically necessary for the indications specified in this policy when ALL of the following criteria are met:

1. Patient meets one of the following:
    a) Both of the following:
        - History of a trial of at least 14 weeks of Avsola, Inflectra or Renflexis resulting in minimal clinical response; and
        - Physician attests that in his or her clinical opinion, the clinical response would be superior with Remicade than experienced with Avsola, Inflectra or Renflexis.
    b) Or, both of the following:
        - Patient has a history of intolerance, contraindication, or adverse event to either Avsola, Inflectra, Renflexis, or other infliximab biosimilar products; and
        - Physician attests that in his or her clinical opinion the same intolerance, contraindication, or adverse event would not be expected to occur with Remicade; and
2. Patient has not had a loss of a favorable response after established maintenance therapy with Avsola, Inflectra, Renflexis, or other infliximab biosimilar product; and
3. Patient meets the infliximab diagnosis-specific criteria for the requested indication.

Diagnosis-Specific Criteria

The term infliximab in the Diagnosis-Specific Criteria refers to Remicade and all infliximab biosimilar products. Infliximab is medically necessary when the diagnosis-specific criteria for the below requested indications are met:

- Ankylosing spondylitis (AS)
- Inflammatory bowel disease (IBD)
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis (RA) in combination with methotrexate

CLINICIAN ADMINISTERED DRUGS – SITE OF CARE

The Clinician Administered Drugs – Site of Care guideline applies to medication infusion services provided by hospital outpatient facilities to patients who are ≥ 18 years of age with the following Place of Service codes:

- 19 - Off Campus-Outpatient Hospital; and
- 22 - On Campus-Outpatient Hospital

Infusion services provided to patients < 18 years of age are not subject to this policy

The following alternative non-hospital sites of care are preferred, and should be used for medication infusion therapy if clinically appropriate in non-emergency situations for patients who are considered medically stable:

- Non-hospital outpatient infusion centers

- Physician office
- Ambulatory infusion centers
- Home infusion services

Community will provide coverage for medication infusion services in hospital-based outpatient infusion facilities for patients who meet the requirements for Hospital-based Outpatient Infusion criteria. This policy applies only to the site of care where the patient receives the infusion. Additional prior authorization approval may be required for the requested medication.

Hospital-based Outpatient Infusion Criteria

Medication infusion in a hospital outpatient setting is medically necessary for patients who meet at least one of the following requirements:

- Documentation showing severe or potentially life-threatening adverse events from previous infusions that were not successfully managed through pre-medications (e.g., acetaminophen, diphenhydramine, steroids, etc.)
- Patient has complex medical status or therapy that requires monitoring or potential intervention beyond the capabilities of the alternative non-hospital sites of care
- Patient has condition(s) that increase(s) risk for severe adverse event (e.g., cardiopulmonary disorder, fluid overload status, unstable renal function, unstable vascular access)
- Patient is unable to adhere to treatment at an alternative non-hospital site of care due to physical or cognitive impairment
- First infusion, or to re-initiate therapy after at least 6 months of no infusion
- If the provider cannot infuse in the office setting, attestation from the prescriber that the patient's home environment is not suitable for home infusion therapy

Approval for medication infusion in a hospital outpatient setting will be limited to 6 months to allow for reassessment of the patient's ability to receive treatment at an alternative non-hospital site of care.

You will find a complete description of each of these guidelines in our provider portal.