Effective Date: 10/01/2021
Last Approval/Version: 01/2024
Next Review Due By: 01/2025
Policy Number: C22068-A

Fasenra (benralizumab), IL Medicaid Only

PRODUCTS AFFECTED

Fasenra (benralizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label along with state and federal requirements, benefits being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

INITIAL AUTHORIZATION:

1. Documentation diagnosis of moderate to severe asthma with eosinophils greater than or equal to 150 cell/microliter. [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attestation that Fasenra will be used as add-on maintenance therapy (not prescribed for monotherapy)

AND

3. Prescriber attests or clinical reviewer has found that member has had an exacerbation requiring oral or systemic corticosteroid treatment while on maintenance therapy for asthma (e.g. inhaled corticosteroids and long-acting beta-2-agonist)
   Molina Reviewer Note: Please review claims history for use of oral or systemic corticosteroids in the previous 12 months.

CONTINUATION OF THERAPY:

Prescriber attestation of positive response to therapy

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
12 years of age and older

QUANTITY: See Illinois Medicaid Drug Formulary or use maximum quantity per FDA label

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit (Fasenra Pen, Autoinjector) or medical benefit (Fasenra, Syringe) coverage and the subcutaneous injectable products be administered in a place of service that is a non-hospital facility-based location or patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-5 Antagonists (IgG1 kappa)

FDA-APPROVED USES:

Fasenra (benralizumab): interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
Limitations of Use:

- Not for treatment of other eosinophilic conditions
- Not for relief of acute bronchospasm or status asthmaticus

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Fasenra (benralizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Fasenra (benralizumab) include known hypersensitivity to benralizumab or any of its excipients.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0517	Injection, benralizumab, 1 mg

AVAILABLE DOSAGE FORMS:

Fasenra Pen SOAJ 30MG/ML
Fasenra SOSY 30MG/ML

REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 01/01/2024
2. Illinois Medicaid Preferred Drug List, Effective January 1, 2024
3. Fasenra (benralizumab) [prescribing information], Wilmington, DE: AstraZeneca Pharmaceuticals LP., February 2021
4. Bleecker, E. R., FitzGerald, J. M., Chanez, P., Papi, A., Weinstein, S. F., Barker, P., Sproule, S., Gilmartin, G., Aurivillius, M., Werkström, V., Goldman, M., & SIROCCO study investigators (2016). Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β2-agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet (London, England), 388(10056), 2115–2127. https://doi.org/10.1016/S0140-6736(16)31324-1
5. FitzGerald, J. M., Bleecker, E. R., Nair, P., Korn, S., Ohta, K., Lommatzsch, M., Ferguson, G. T., Busse, W. W., Barker, P., Sproule, S., Gilmartin, G., Werkström, V., Aurivillius, M., Goldman, M., & CALIMA study investigators (2016). Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet (London, England), 388(10056), 2128–2141. https://doi.org/10.1016/S0140-6736(16)31322-8

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW - Notable revisions: Diagnosis Required Medical Information Place of Administration References	01/2024
Annual updates.	02/2022
New criteria creation.	10/2021