DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Fasenra Drug Quantity Management Policy – Per Days
- Fasenra® (benralizumab subcutaneous injection – AstraZeneca)

REVIEW DATE: 07/17/2024; selected revision 09/25/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Fasenra, an interleukin-5 receptor alpha (IL-5Rα)-directed cytolytic monoclonal antibody, is indicated for the following uses:[1]
- **Asthma** as add-on maintenance treatment of patients ≥ 6 years of age with severe disease and an eosinophilic phenotype. Limitations of Use: Fasenra is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm/status asthmaticus.
- **Eosinophilic granulomatosis with polyangiitis** (EGPA) in adults.

Dosing

Asthma Dosing
- Adults and adolescents ≥ 12 years of age: 30 mg administered as a subcutaneous (SC) injection once every 4 weeks (Q4W) for the first 3 doses, then once every 8 weeks (Q8W) thereafter.[1]
- Patients 6 to 11 years of age:
  - Weight < 35 kg: 10 mg SC Q4W for the first 3 doses, then Q8W thereafter.
  - Weight ≥ 35 kg: 30 mg SC Q4W for the first 3 doses, then Q8W thereafter.

Eosinophilic Granulomatosis with Polyangiitis Dosing
The recommended dose of Fasenra in patients with EGPA is 30 mg once every 4 weeks.[1]

Availability
Fasenra is available as 10 mg/0.5 mL and 30 mg/mL single-dose, prefilled syringes and a 30 mg/mL single-dose pen.[1] Each carton contains one pen or syringe.

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Fasenra. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals will be provided for the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail and Home Delivery Maximum Quantity per 56 days
Fasenra® (benralizumab subcutaneous injection)	10 mg/0.5 mL prefilled syringes	1 syringe (0.5 mL)
	30 mg/mL prefilled syringes	1 mL (1 syringe)
	30 mg/ mL prefilled pens	1 mL (1 pen)

Immunologicals – Fasenra Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA
Fasenra 10 mg/0.5 mL prefilled syringes

1. If the patient is initiating therapy at induction dosing for asthma, as verified by the absence of claims for Fasenra in the past 130 days, approve a one-time override for 3 syringes (1.5 mL) at retail and home delivery.

Fasenra 30 mg/mL pens and prefilled syringes

1. If the patient is initiating therapy at induction dosing for asthma, as verified by the absence of claims for Fasenra in the past 130 days, approve a one-time override for 3 mL (3 pens or 3 prefilled syringes) at retail and at home delivery.
2. If the patient has eosinophilic granulomatosis with polyangiitis , approve 1 mL (1 pen or 1 syringe) per 28 days at retail and 3 mL (3 pens or 3 syringes) per 84 days at home delivery.

REFERENCES

1. Fasenra® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; September 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/04/2023
Early Annual Revision	**Fasenra 10 mg/0.5 mL prefilled syringes:** New quantity limit of 0.5 mL (1 syringe) per 56 days at retail and home delivery was added to the policy. Clinical override criteria apply.	07/17/2024
Selected Revision	**Fasenra 30 mg/mL pens and prefilled syringes:** A new override for 1 mL (1 pen or syringe) per 28 days at retail and 3 mL (3 pens or syringes) per 84 days at home delivery if the patient has eosinophilic granulomatosis with polyangiitis was added to the policy.	09/25/2024