PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Immunologicals – Anti-Interleukin-5 Agents Preferred Specialty Management Policy
- Cinqair® (reslizumab intravenous infusion – Teva)
- Fasenra® (benralizumab subcutaneous injection – AstraZeneca)
- Nucala® (mepolizumab subcutaneous injection – GlaxoSmithKline)

REVIEW DATE: 11/15/2023

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. 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

Cinqair, Fasenra, and Nucala are anti-interleukin (IL)-5 monoclonal antibodies indicated for add-on maintenance treatment of patients with **severe asthma** who have an eosinophilic phenotype.[1-3] Nucala is indicated in patients ≥ 6 years of age; Fasenra is indicated in patients ≥ 12 years of age; Cinqair is indicated in patients ≥ 18 years of age. Nucala is also indicated for the treatment of adults with eosinophilic granulomatosis with polyangiitis, adults and adolescents with hypereosinophilic syndrome, and adults with chronic rhinosinusitis with nasal polyps.[3]

Guidelines

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management (2023) lists Cinqair, Fasenra, and Nucala as options for add-on therapy with difficult-to-treat, severe eosinophilic asthma (i.e., asthma that cannot be managed by therapy with an inhaled corticosteroid/long-acting beta$_2$-agonist combination

with or without an additional controller).[4] GINA does not prefer one anti-IL-5 agent over another, but does note the differences in their approved age indications.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). If the patient meets the standard *Immunologicals – Cinqair Prior Authorization Policy* criteria, but has not tried a Preferred Product, a review will be offered for a Preferred Product using the respective standard *Prior Authorization Policy* criteria. All approvals are provided for the duration noted in the respective *Immunologicals Prior Authorization Policy*.

Preferred Products: Fasenra, Nucala
Non-Preferred Products: Cinqair

Immunologicals – Anti-Interleukin-5 Agents non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Cinqair	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Immunologicals – Cinqair Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has tried ONE of Fasenra or Nucala; OR **ii.** Patient is currently receiving Cinqair. **2.** If the patient has met the standard *Immunologicals – Cinqair Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B): offer to review for a Preferred Product.

REFERENCES

1. Cinqair® intravenous infusion [prescribing information]. Frazer, PA: Teva; January 2019.
2. Fasenra® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; October 2019.
3. Nucala® subcutaneous injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.

4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2023. Available at: http://www.ginasthma.org. Accessed on October 17, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/02/2022
Annual Revision	No criteria changes.	11/15/2023

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