oscar

Clinical Guideline

Oscar Clinical Guideline: Immunotherapies for Reactive and Obstructive Airway Diseases - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG100, Ver. 2)

Immunotherapies for Reactive and Obstructive Airway Diseases - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan has a Medical Preferred Drug List to encourage use of cost-effective and clinically appropriate physician-administered specialty drugs. Table 1 lists the preferred and non-preferred Immunotherapies for Reactive and Obstructive Airway Diseases:

Table 1: Immunotherapies for Reactive and Obstructive Airway Diseases, Medical Preferred Drug List

Drug Class	*Preferred Products**	*Non-Preferred Products†/**
Immunotherapies for Reactive and Obstructive Airway Diseases	❖ Dupixent (dupilumab) ❖ Fasenra (benralizumab) ❖ Nucala (mepolizumab) ❖ Tezspire (tezepelumab-ekko) ❖ Xolair (omalizumab)	❖ Cinqair (reslizumab)

[ℕ]subject to Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria.

[*]*Other drug-specific or class-specific clinical guidelines may also be applicable.*

- *Products considered Formulary or Preferred for the Plan may still require a clinical prior authorization review.*
- *The Plan may review all requests made under the Medical or Pharmacy benefit against specific prior authorization criteria, as applicable and at its discretion.*

This policy outlines the Plan's preferred products and exception criteria for non-preferred products through prior authorization. The coverage review process will determine if a clinical exception can be made.

- The program applies to all members requesting treatment with a non-preferred product (see Table 1).
- Preferred drugs are selected based on clinical effectiveness, safety, FDA approval, and treatment guidelines. In most cases, preferred medications must be tried first as long as they are considered safe and effective by the provider.
- Requests for non-preferred medications may require meeting Medical Benefit Preferred Drug Exceptions Criteria. Approval may be given if the member has tried and failed, or cannot use the Plan's preferred drug(s). Exceptions may include, but are not limited to the following:
    1. The member has a documented trial and failure, inadequate response, intolerance, or contraindication to ALL preferred drug(s), as applicable; ***or***
    2. The member has a risk factor(s) for poor response to the preferred drug(s); ***or***
    3. The member is not a candidate for the preferred drug(s) based on the member's condition(s), individual needs, treatment history, or accepted standards of medical practice.

For more information or to request an exception, please contact the Plan.

Definitions

"**Compendia**" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"**Contraindication**" refers to a pre-existing condition or factor that precludes use of a drug due to risk of harm.

"**Intolerance**" refers to the inability to tolerate or endure something, often due to experiencing subjectively difficult or harmful side effects, reactions, or hypersensitivities when using a medication or treatment that negatively impacts quality of life, ability to adhere, or overall health. Documentation is expected to detail the specific intolerable effects and their impact on treatment.

"**Documentation**" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;
2. Prescription claims records, and/or prescription receipts to support prior trials of alternatives.

"**Experimental or Investigational**" are procedures, drugs, or devices that haven't been proven effective or which haven't been approved by the appropriate regulatory bodies.

"**FDA**" refers to the Federal Food and Drug Administration.

"**Medical Benefit Preferred Drug Exceptions Criteria**" are Plan requirements that must be met for a non-preferred drug to be approved for coverage, such as trial and failure of preferred drugs first.

State Law Conflicts

For any provision of this policy that directly conflicts with or is prohibited by state law, the provisions of the state law will apply instead of the provisions of this policy. This means that in instances where state regulations diverge from or directly oppose the Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria or requirements, the policy's criteria will not apply.

Exception Criteria

The Plan considers the **Non-Preferred Product** to be medically necessary when the member meets **BOTH** of the following criteria:

1. Inadequate response or treatment failure with at least **THREE**⇶ FDA, compendia, or evidence-based guideline-supported preferred products that are indicated and clinically appropriate for the diagnosis, unless:

a. The member experienced an intolerable adverse event to **THREE**⇶ preferred products***; or***

b. The member has a contraindication to **ALL** preferred products***; AND***

⇶*If there are less than three preferred products indicated and clinically appropriate, the member must have an inadequate response, adverse event, or contraindication to ALL that are available.*

2. Clinical documentation is provided showing:
    a. The specific reason(s) why preferred products cannot be used (e.g. inadequate response, adverse event, contraindication)***; and/or***
    b. Relevant clinical information supporting the use of the requested Non-Preferred Product (e.g. office notes, lab results, diagnostic reports).

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Self-Administered Formulation Exception Criteria

The Plan considers the **physician-administered formulation of a product that has a self-administered formulation available** (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair) to be medically necessary when the member meets **ONE** of the following criteria:

1. The member has a documented contraindication to the self-administered formulation of the same product that would **NOT** be expected to occur with the physician-administered formulation***; OR***
2. The member experienced a documented intolerable adverse event to the self-administered formulation of the same product that would **NOT** be expected to occur with the physician-administered formulation***; OR***
3. The member requires administration by a trained healthcare professional due to one of the following:
    a. The member is initiating therapy with the requested product***; or***
        - ➢ *Initial approval will be for 1 month for Dupixent, Fasenra, Nucala, and Tezspire, and 3 months for Xolair to allow for proper self-administration training, assessment of the member's ability to self-administer, and monitoring of allergic reactions (for Xolair).*
        - ➢ *Continued approval beyond the initial period will require documentation of inability to self-administer despite proper training.*

b. The member is less than 12 years of age and does not have a caregiver who can be properly trained to administer the medication***; or***
c. The member has physical or cognitive limitations that prevent self-administration, including but not limited to visual impairment, limited manual dexterity, or impaired cognitive function***; or***
    - ➢ Documentation of the specific limitation and why it prevents self-administration is required
d. The member requires a dose or dosage form that is not available or feasible for self-administration (e.g., requires multiple injections per dose, requires a dose that exceeds the maximum dose per injection for self-administered formulations, requires reconstitution from a vial)**.**

<u>If one of the above self-administered formulation exception criteria are met, the physician-administered formulation will be approved as follows:</u>**

1. **For members with a contraindication, intolerable adverse event, or dose/dosage form limitations (criteria 1, 2, or 3d), the authorization will be for up to 12 months.**
2. **For members initiating therapy (criteria 3a), an initial 1-month authorization will be granted for Dupixent, Fasenra, Nucala, and Tezspire, and a 3-month authorization for Xolair. Continued authorization beyond the initial period will require documentation that the member remains unable to self-administer despite proper training.**
    - ***For Xolair (omalizumab):***
        - *i. **Initial authorization for 3 months for all new starts, regardless of age, for monitoring of allergic reactions.***
        - *ii. **Continued authorization beyond 3 months requires meeting one of the above criteria (1, 2, 3b, 3c, or 3d).***
    - ***For Dupixent (dupilumab), Fasenra (benralizumab), Nucala (mepolizumab), and Tezspire (tezepelumab-ekko):***
        - *i. **Initial authorization for 1 month.***
        - *ii. **A single 1-month extension may be granted with appropriate documentation if additional time is needed for training or transition to self-administration.***
3. **For members under 12 years old without a trained caregiver or with physical/cognitive limitations preventing self-administration (criteria 3b-c), authorization will be for 12 months. For members under 12, annual reauthorization will require documentation that the member remains unable to self-administer and does not have a caregiver who can be properly trained to administer the medication.**

- ***For pediatric* members *aged 6-11 years, a stepwise approach to transitioning to self-administration should be considered, with re-evaluation at each renewal.***

NOTE - on Continuation of Therapy:

- *After the initial approval period (1 month for Dupixent, Fasenra, Nucala, and Tezspire; 3 months for Xolair), if the member is able to transition to self-administration, subsequent therapy will be approved through the member's pharmacy benefit for the remainder of a 12-month total authorization period.*
- *The total authorization period (including both medical and pharmacy benefit coverage) will not exceed 12 months before requiring re-evaluation.*
- *Transition to the pharmacy benefit for self-administered formulations should be initiated as soon as the member is able to safely self-administer or have a caregiver administer the medication.*

NOTE - for all approvals:

- *The Plan reserves the right to require periodic re-evaluation of the need for physician administration for all members receiving long-term approval.*
- *The prescriber must attest that they have assessed and will continue to assess the member's ability to self-administer or have a caregiver administer the medication.*

Experimental or Investigational / Not Medically Necessary

The Plan does not cover non-preferred products when used for experimental, investigational, or medically unnecessary indications. Use of non-preferred products is considered experimental, investigational, or not medically necessary if the indication is outside FDA-approved labeling or not supported by current medical evidence and standards of care. The Plan does not cover non-preferred products for the following non-approved indications (not all-inclusive):

1. Uses not considered clinically appropriate based on indication, including age, dosing (dosage, frequency, duration of therapy, and site of administration), and contraindication.
    a. Non-FDA approved indications or off label use without sufficient evidence supporting safety and efficacy
    b. Doses exceeding the FDA-approved label or clinical practice guidelines without sufficient evidence supporting safety and efficacy
2. Uses not required for treatment or management of the member's medical condition.
3. Uses not aligned with generally accepted medical practice.
4. Uses primarily for the convenience of the member, family, or provider.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
J0517	Fasenra Injection, benralizumab, 1 mg
J2182	Nucala Injection, mepolizumab, 1 mg
J2356	Tezspire Injection, tezepelumab-ekko, 1 mg
J2357	Xolair Injection, omalizumab, 5 mg
J2786	Cinqair Injection, reslizumab, 1 mg
C9399	Dupixent (dupilumab) Unclassified drugs or biologicals
J3590	Dupixent (dupilumab) Unclassified biologics

References

1. Cinqair (reslizumab) [prescribing information]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; October 2022.
3. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
4. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/2023-gina-main-report/. Updated 2023.
5. Nucala (mepolizumab) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; January 2022.
6. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; February 2023.
7. Xolair (omalizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; March 2023.

Clinical Guideline Revision / History Information

Original Date: 12/14/2023 Reviewed/Revised: 06/27/2024