Medical Drug Clinical Criteria

Subject:	Adbry (tralokinumab)		
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Overview

This document addresses the use of Adbry (tralokinumab), an injectable, selective interleukin (IL)-13 antagonist.

Per the American Academy of Dermatology (AAD 2014) AD, the most common form of eczema, affects approximately 2% to 3% of adults and 25% of children. AD is frequently associated with a personal or family history of allergies, allergic rhinitis and asthma. AD typically follows a relapsing/chronic course but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and crusting, or lichenification. While there is no accepted standardized method of classifying disease severity, categorization is usually based upon objective disease features, extent of skin involvement and possibly subjective disease features. Due to the impaired skin integrity, affected individuals are more susceptible to skin infections.

Guidelines from the AAD regarding the treatment of AD recommend non-pharmacologic therapy, pharmacologic therapy and phototherapy (AAD 2014). Non-pharmacologic therapy includes use of moisturizers (I, A) and use of wet wrap therapy with or without a topical corticosteroid for those with moderate to severe AD during flares (II, B). First line topical pharmacologic therapy are topical corticosteroids (I, A). Labeled dosage guidance from high dose topical steroids recommend limiting consecutive use to 2 weeks (Ultravate 2020, Diprolene 2019). Topical calcineurin inhibitors are recommended for use on actively affected areas as a steroid sparing agent (I, A). Labeled dosage guidance for Elidel and Protopic recommend re-evaluation if signs and symptoms persist beyond 6 weeks of use (Elidel 2017, Protopic 2019). Phototherapy is recommended as a second line treatment, after failure of first-line treatment (topical therapy) (II, B). In addition, phototherapy can be used as maintenance therapy in those with chronic disease. Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate) are indicated when individuals have disease symptoms not controlled by optimized topical regimens and/or phototherapy (I,II, B). The guidelines have not been updated to address the use of any biologic agent.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Adbry (tralokinumab)

Initial requests for Adbry (tralokinumab) for the treatment of atopic dermatitis may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
III. Individual meets *one* of the following (A or B):
    A. Failure of topical pharmacological therapy as indicated by **both** (1 and 2) of the following:
        1. Daily treatment of topical corticosteroids of medium to higher potency for at least fourteen (14) days has failed to achieve and maintain remission of low or mild disease activity state; **OR**
            a. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (AAD 2014):
                i. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**
                ii. Individual has steroid-induced atrophy; **OR**
                iii. History of long-term or uninterrupted topical steroid use;

    AND

2. Documentation is provided that daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**
    a. Documentation is provided that topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:
        i. History of or active malignant or pre-malignant skin conditions; **OR**
        ii. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**
        iii. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis;

OR

B. One of the following:
    1. Documentation is provided that phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated; **OR**
    2. Documentation is provided that non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) have failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

Continuation requests for Adbry (tralokinumab) for atopic dermatitis after 6 months may be if approved if the following criterion is met:

I. Treatment with Adbry (tralokinumab) has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life)

Adbry (tralokinumab) may not be approved for the following:
I. In combination with oral or topical JAK inhibitors; **OR**
II. In combination with biologic immunomodulators; **OR**
III. In combination with other immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
IV. When the above criteria are not met and for all other indications.

Initial approval duration: 6 months
Continuation approval duration: 12 months

Quantity Limits

Adbry (tralokinumab) Quantity Limits

Drug	Limit
Adbry (tralokinumab) 150 mg syringe*	2 syringes per 28 days

* For Adbry Initiation of therapy: May approve six (6) -150 mg syringes in the first month of therapy for initiation dose and first maintenance dose, then four (4) -150 mg syringes for the following five months of maintenance therapy for a total of twenty-six (26) -150 mg syringes in the first six months of therapy

For Adbry maintenance therapy:
I. Continue authorization for one year with four (4)- 150 mg syringes per 28 days if the following are met:
    A. Individual weighs 100 kg or more;
    OR
    B. Individual weighs less than 100 kg; **AND**
        1. One of the following is met:
            a. Individual has not achieved clear to almost clear skin in the last 6 months; **OR**
            b. Provider submits documentation providing rationale for the four (4) -150 mg syringes per 28 days dosing (i.e. patient did not achieve or maintain clear or almost clear skin); **OR**
            c. Provider submits supporting documentation that the member has tried two (2) - 150mg syringes per 28 days dosing and did not achieve or maintain clear or almost clear skin.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement

policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
J3490	Unclassified drugs (when specified as [Adbry] (tralokinumab)
J3590	Unclassified biologics (when specified as [Adbry] (tralokinumab)
C9399	Unclassified drugs or biologicals (when specified as Adbry] (tralokinumab)

ICD-10 Diagnosis	
	All diagnoses pend

Document History

Revised: 08/19/2022
Document History:

- 08/19/2022 – Annual Review: Update do not approve criteria, update quantity limit override. Coding Reviewed: No changes.
- 06/13/2022 – Select Review: Update do not approve criteria, update quantity limit override criteria. Coding Reviewed: Added HCPCS C9399. Effective 8/1/2022 Added HCPCS J3590.
- 02/25/2022– Select Review: Clarify systemic therapy, modify do not approve criteria, wording and formatting changes. Coding Reviewed: No changes.
- 01/04/2022 – Select Review: Add new clinical criteria and quantity limit for Adbry. Coding Reviewed: Added HCPCS J3490. All diagnoses pend.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 21, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Atopic Dermatitis Clinical Guideline. Guidelines of care for the management of atopic dermatitis. Journal of the American Academy of Dermatology. 2014. Available at https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis. Accessed on June 21, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.