Oscar Clinical Guideline: Eucrisa (crisaborole) (PG023, Ver. 7)

Eucrisa (crisaborole)

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

Atopic dermatitis (AD), commonly known as eczema, is a chronic, inflammatory skin disorder primarily characterized by intense itching, redness, and eczematous lesions, which can be accompanied by skin dryness, scaling, and thickening. It affects approximately 10% of adults and 20% of children worldwide. Its pathology involves a combination of skin barrier dysfunction, immune dysregulation, and environmental and genetic factors. AD is often associated with other atopic disorders such as asthma and allergic rhinitis.

AD presents differently across age groups, with acute, subacute, and chronic stages. In infants and toddlers, it typically affects the face, scalp, and extensor surfaces of the extremities, while in older children and adults, it tends to localize to the flexural areas. It is a relapsing disease, with flares commonly triggered by irritants, allergens, infections, and stress.

Standard treatment of AD involves a combination of skin care practices, trigger avoidance, and pharmacologic interventions. The cornerstone of AD management includes regular use of moisturizers to enhance the skin barrier and reduce dryness and pruritus. Mild to moderate AD is typically managed with topical medications, which may include topical corticosteroids and calcineurin inhibitors such as tacrolimus. More severe cases may necessitate systemic treatments such as systemic corticosteroids, immunosuppressants, or newer biologic therapies.

Eucrisa (crisaborole) is a non-steroidal, anti-inflammatory phosphodiesterase-4 inhibitor for topical use. It has been approved for the treatment of mild to moderate atopic dermatitis in patients aged 3 months and older. Crisaborole works by reducing inflammation and increasing hydration in the skin. Its primary advantage is its safety profile, which is notably devoid of the adverse effects commonly associated with prolonged use of topical corticosteroids, such as skin atrophy. The most common side effect is skin irritation at the application site, including symptoms such as pain, burning, or stinging.

Definitions

"Atopic Dermatitis" also known as eczema is a chronic skin condition that makes a person's skin red, itchy and scaly. Atopic dermatitis (AD) often begins during childhood and persists into adulthood. Some people experience occasional flares followed by periods of improvement or a "waxing and waning" course of the disease.

"Biologics" "Biologicals" or "Biological therapeutics"as defined by the World Health Organization (WHO) are a class of medicines which are grown and then purified from large-scale cell cultures such as bacteria, yeast, animal or plant cells. Biologics can include but are not limited to vaccines, growth factors, immune modulators, and monoclonal antibodies. Unlike other medicines, biologics are generally proteins purified from living culture systems and/or blood, and are often referred to as "large modules."

"Body surface area (BSA)" is a measure of the total area involved by plaques in relation to the total body surface area. There are a number of different methods, however most clinical trials on plaque psoriasis use the "handprint method", where the patient's actual palm/hand size is estimated as 1% of BSA. The head and neck, upper extremities, trunk, and lower extremities (including buttocks) typically correspond to approximately 10%, 20%, 30% and 40% of the BSA, respectively.

"Calcineurin Inhibitors" are immunomodulating drugs used topically in the management of atopic dermatitis, such as tacrolimus and pimecrolimus. They suppress the activity of the immune system and decrease inflammation, but are generally used when topical corticosteroids are ineffective or contraindicated.
"Erythema" refers to the redness of the skin caused by increased blood flow in the superficial capillaries. In atopic dermatitis, erythema is a sign of inflammation.

"Excoriation" refers to chafing, picking, scratching or scraping of the skin, resulting in raw, irritated and sometimes painful lesions."Exudation" is the oozing of fluid, usually serous fluid, which can occur in acute phases of atopic dermatitis when vesicles or blisters rupture.

“Induration’” refers to the thickening of tissues, usually due to inflammation or edema. This commonly occurs on the hands and face, but can occur on the chest, back, abdomen, breasts and buttocks.

"Lichenification" refers to skin thickening with accentuation of skin markings, often a consequence of chronic scratching or rubbing in conditions like atopic dermatitis.

“Papulation” refers to the process of papule (a small, solid, raised bump) formation on the skin.

"Pruritus" refers to itchiness, a common and distressing symptom of atopic dermatitis that can significantly affect quality of life.

"Topical Corticosteroids" are medications applied directly to the skin to reduce inflammation and irritation. They are a mainstay of treatment for atopic dermatitis but can have side effects with prolonged use, such as skin thinning.

"Xerosis" refers to abnormally dry skin, a characteristic feature of atopic dermatitis. Regular use of moisturizers is recommended to combat xerosis in AD management.

Medical Necessity Criteria for Initial Authorization

The Plan considers Eucrisa (crisaborole) medically necessary when ALL of the following criteria are met:

1. The member has a diagnosis of mild to moderate atopic dermatitis; *AND*
2. The member meets ONE of the following:
    a. is unable to use, or has tried and failed BOTH of the following:
        i. a topical corticosteroid; *and*
        ii. a topical calcineurin inhibitor (such as tacrolimus); *or*
    b. requires treatment in an affected area that is considered sensitive (such as the face, axillae, skin fold, or groin) AND the member is unable to use, or has tried and failed a topical calcineurin inhibitor (such as tacrolimus).

If the above prior authorization criteria are met, Eucrisa (crisaborole) will be approved for up to 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization of Eucrisa (crisaborole) for a period of up to 12 months will be granted if the member demonstrates a positive clinical response to therapy, as evidenced by ANY of the following:

1. Reduction in body surface area involvement of atopic dermatitis lesions; *OR*
2. Decrease in pruritus severity; *OR*
3. Improvement in signs and symptoms of atopic dermatitis, such as erythema, exudation, excoriation, induration/papulation, and lichenification.

Experimental or Investigational / Not Medically Necessary

Eucrisa (crisaborole) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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