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| <b>Trade Name (generic)</b>  |                       |
| EUCRISA (crisaborole) topical ointment   | Indication not funded |
| <b>Indications</b>   |                       |
| <ul style="list-style-type: none"> <li>Topical treatment of mild to moderate atopic dermatitis (AD) in patients <math>\geq 2</math> years of age.</li> </ul>   |                       |
| <b>Dosage</b>  |                       |
| <ul style="list-style-type: none"> <li>2% (20 mg/gram) topical ointment</li> <li>Thin layer applied topically twice daily to affected areas (not for ophthalmic, oral, or intravaginal use)</li> </ul>   |                       |
| <b>Background</b>  |                       |
| <ul style="list-style-type: none"> <li>Crisaborole is a new molecular entity that inhibits phosphodiesterase 4, resulting in increased intracellular cAMP levels. Its mechanism of action is not well defined.</li> <li>Other drug treatments for AD include topical corticosteroids and topical calcineurin inhibitors.</li> </ul>  |                       |
| <b>Efficacy</b>  |                       |
| <ul style="list-style-type: none"> <li>In two identically designed, multicenter, double-blind, phase 3 studies (AD-301 and AD-302), 1522 United States patients 2 to 79 years old with mild to moderate AD were randomly assigned 2:1 to crisaborole or vehicle-control applied twice daily for 28 days.</li> <li>Baseline characteristics: <ul style="list-style-type: none"> <li>86.3% were age 2 to 17 years, 56% were male, 61% were White, 28% were Black</li> <li>Treatable body surface area was 5% to 95% (mean 18.3%)</li> <li>38.5% had an Investigator's Static Global Assessment (ISGA) score of 2 (indicating mild severity) and 61.5% had a score of 3 (indicating moderate severity)</li> </ul> </li> <li>Primary end point was the proportion of patients with an ISGA score at day 29 of clear (0) or almost clear (1) skin with at least a 2-grade improvement from baseline: <ul style="list-style-type: none"> <li>Trial AD-301: 32.8% of crisaborole group (n=503) vs. 25.4% of vehicle group (n=256), p=0.038; NNT = 14</li> <li>Trial AD-302: 31.4% of crisaborole group (n=513) vs. 18% of vehicle group (n=250), p&lt;0.001; NNT = 8</li> </ul> </li> </ul> |                       |
| <b>Safety</b>  |                       |
| <ul style="list-style-type: none"> <li><b>Adverse reactions:</b> Application site pain (3%), contact urticarial (&lt;1%)</li> <li><b>Contraindications:</b> Known hypersensitivity</li> <li><b>Warnings and precautions:</b> Hypersensitivity reactions</li> </ul>   |                       |
| <b>Evidence Gaps/Limitations</b>   |                       |
| No studies found to support evidence for use in the treatment of Oregon Health Plan (OHP) funded conditions or co-morbidities.   |                       |
| <b>Recommendation</b>  |                       |
| Restrict use for OHP-funded conditions through Prior Authorization.  |                       |
| <b>References</b>  |                       |
| <ol style="list-style-type: none"> <li>Eucrisa (crisaborole) [prescribing information]. Palo Alto, CA: Anacor Pharmaceuticals, Inc; December 2016.</li> <li>Paller AS, Tom WL, Lebwohl MG, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. <i>Journal of the American Academy of Dermatology</i>. 2016;75(3):494-503.</li> </ol>  |                       |