CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

roflumilast (Zoryve)

Arcutis Biotherapeutics, Inc.

Indication: ZORYVE™ (roflumilast cream, 0.3%) is indicated for topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older.

August 3, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0771
Name of the drug and Indication(s)	Roflumilast (Zoryve) for plaque psoriasis
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	☐
	No requested revisions	X☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0771
Brand name (generic)	ZORYVE (roflumilast cream 0.3%)
Indication(s)	For topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older
Organization	Arcutis Biotherapeutics, Inc. (Arcutis)
Contact information[a]	Name: Clarabella Yim Title: Director, Market Access Email: [redacted] Phone: [redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Arcutis agrees with the committee's assessment that roflumilast demonstrated improved overall severity of psoriasis on the body and psoriasis of the intertriginous areas, as well as the extent and severity of psoriasis, and the severity of itch compared to vehicle. Furthermore, Arcutis agrees that roflumilast *"may meet an unmet need for patients living with plaque psoriasis in the intertriginous areas"* and that roflumilast *"may provide an alternative, non-steroidal topical treatment option for patients living with plaque psoriasis, including psoriasis in the intertriginous area"*.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

Arcutis agrees that the recommendation reflects patient and clinician input, as "*patients identified a need for alternative topical treatments that are effective, have few side effects, are better tolerated for patients with intertriginous involvement, and can be used long-term for this chronic condition"*. The clinical expert consulted by CADTH *"suggested that they would consider roflumilast as an alternative to other first-line topical treatments for psoriasis within the current stepped approach that could prevent patients from stepping up to systemic therapy",* and that *"roflumilast may be preferred for long-term use in some patients and clinicians given that it is not a steroid".*

Patients and clinicians identified an unmet need for patients who experience intertriginous psoriasis, and CADTH acknowledged the unmet need, stating that "*there are many topical options available for the treatment of plaque psoriasis, but the treatment of intertriginous areas may represent an area of unmet need".*

However, the benefit roflumilast provides to patients with intertriginous psoriasis was not considered in CADTH's assessment of the price reduction required to be cost effective relative to topical corticosteroids. ZORYVE is the only product approved by Health Canada for intertriginous psoriasis and therefore provides a unique benefit to patients relative to topical corticosteroids. Arcutis believes that this benefit should be reflected in the cost-effectiveness and price analyses. Furthermore, topical calcineurin inhibitors are not approved by Health Canada for the treatment of plaque psoriasis;

however, they are recommended in Canadian guidelines and used off-label in clinical practice to treat psoriatic plaques in the intertriginous areas. Notably, roflumilast is priced lower per gram than topical calcineurin inhibitors.
Clarity of the draft recommendation
3. Are the reasons for the recommendation clearly stated? — Yes ☒ / No ☐
Arcutis believes the reasons for the recommendation are clearly stated.
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation? — Yes ☒ / No ☐
Arcutis believes the implementation issues have clearly been articulated and adequately addressed in the recommendation.
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation? — Yes ☒ / No ☐
Arcutis believes the reimbursement conditions and rationale for the conditions are clearly stated in the recommendation.

[a] CADTH may contact this person if comments require clarification.