CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

SOMATROGON (Ngenla)

(Pfizer Canada ULC)

Indication: Growth hormone deficiency

December 2, 2021

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0683
Name of the drug and Indication(s)	Somatrogon (Ngenla) for long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency)
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	X
	No requested revisions	☐

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. • Can “the least costly somatropin” be removed from the last sentence under Pricing – Reason? Genotropin may not be the least costly somatropin in all jurisdictions.
c) Implementation guidance

- Clarify whether consideration for funding can be given to off-label indications (i.e., patients with chronic renal failure, Turner syndrome, idiopathic short stature, Prader-Willi syndrome, or adult growth hormone deficiency?) and children < 3 years of age.
- Clarify how bone age is assessed.
- Clarify whether epiphyseal growth plate fusion be a substitute for bone age.
- Clarify whether there is variability in age when the epiphyseal plates fuse.
- Clarify whether consideration can be given on a case-by-case basis for renewals where a patient's epiphyseal growth plates have closed but continue to meet height velocity requirement.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.