Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch

Product Listing Agreements

The Ministry of Health will consider confidential product listing agreements (PLAs) for single-source products. These types of agreements result in better value for public funds spent on drugs and assist in managing the financial risk associated with drugs listed on the Saskatchewan Formulary. The ensuing cost savings help to offset Drug Plan expenditures and/or are available to provide additional benefits.

PLAs are considered when product cost is the key barrier to obtaining a Saskatchewan Formulary listing, or in situations where a PLA will address uncertainty in the budget impact, drug utilization, or clinical outcomes.

The Ministry supports and depends on the expert advice of the national and provincial drug review committees. Saskatchewan is also a member of the Pan-Canadian Pricing Alliance whose goals are to:

- Increase access to drug treatment options.
- Improve the consistency of drug listing decisions across the country.
- Capitalize on combined buying power of jurisdictions.
- Achieve consistent pricing and lower drug costs.
- Reduce duplication of negotiations and improve utilization of resources.

The Ministry may agree to meet with a manufacturer regarding its product prior to a recommendation being made by the national drug review committee for the product, or its consideration by the Pan-Canadian Pricing Alliance. However final decisions related to listing will take place after the drug review process and pricing discussions for the product are complete.

For Saskatchewan specific PLAs[1] (i.e., for those products not being considered by the Pan-Canadian Pricing Alliance), manufacturers may present a variety of options to the province including but not limited to price discount, risk sharing, utilization management, coverage with evidence development, health research investment, and health outcomes-based agreements.

PLA discussions may be prioritized based on the Ministry's strategic plans and objectives.

PLAs are not required for all products being submitted for a Saskatchewan Formulary listing.

PLA Submission Requirements[1]

[1] For products being considered through the Pan-Canadian Pricing Alliance, the requirements for the submission are currently determined by the lead province.

The following submission requirements pertain to PLA submissions made by a manufacturer of a single source product to the Ministry. Completion of a Saskatchewan specific form is not required however the submission format should include the elements indicated, and follow the order noted below:

1. Executive summary.
2. Detailed description of the PLA being proposed.
3. Benefit status that is being requested (i.e. Full Formulary or Exception Drug Status with criteria).
4. Rationale clearly stating how the value of the PLA offsets the impact to the Ministry budget, including the benefit of listing the product compared to currently listed products if applicable.
5. Cost impact projections, including the net projected benefit.
6. Term of the offer (note: the typical PLA term in Saskatchewan is 3 years) and any provision for renewal after the initial term.
7. Designation from the manufacturer as to which information and/or content of the PLA submission it considers to be confidential[2] business information.
8. Any additional information the manufacturer would ask the Ministry to consider.

Notes

- In the case where a PLA submission is made for a drug that is not currently listed on the Saskatchewan Formulary, the drug will not be added to the Formulary until the PLA has been executed by all parties.

- By receiving a PLA submission, the Ministry is not obligated to enter into negotiations regarding the PLA. Also, if the Ministry enters into PLA negotiations it may withdraw from the negotiations at its discretion, by providing notification to the manufacturer.

- The Ministry of Health will also consider PLAs for currently listed single source products.

- PLA proposals concerning products currently listed in the Saskatchewan Cancer Agency's (SCA) drug formulary should be made to the SCA.

[2] **The Saskatchewan Ministry of Health recognizes the importance of protecting each participating Manufacturer's confidential business information. The PLA proposal will provide the opportunity for a manufacturer to expressly designate which information and/or content of the PLA submission it considers to be confidential business information. In the absence of the Manufacturer's prior written consent, and except as required by applicable legislation, the Manufacturer's confidential business information may not be disclosed by the Saskatchewan Ministry of Health to any other party. In the event that the Manufacturer's confidential business information may be required to be disclosed pursuant to applicable legislation, the Saskatchewan Ministry of Health will provide the Manufacturer with reasonable notice of any potential disclosure, and, prior to any disclosure, will also provide the manufacturer with a reasonable opportunity to make representations with respect to the information's confidentiality to the Ministry, the Office of the Saskatchewan Information and Privacy Commissioner, or to other relevant government agencies.**