SECTION 2

Price Policy

ADBL - Updated Price Policy
Effective February 23, 2023

PRICE POLICY

DEFINITIONS

In this Price Policy,

Alberta Blue Cross or ABC or Blue Cross means the ABC Benefits Corporation,

Alberta Drug Benefit List, List or ADBL means, unless otherwise indicated, the most recent drug benefit list (including drug benefit listing policies and processes and benefit supplements) published by the Minister from time to time,

Alberta Price Confirmation, APC or Interim APC means an electronic Alberta Price Confirmation process that may be issued by the Minister from time to time and administered by ABC on behalf of the Minister,

APC Terms and Conditions means the terms and conditions outlined in a Non-Fixed Price APC, Fixed Price APC, Pan-Canadian Select Molecule Price Initiative APC, Interim Non-Fixed Price APC or an Interim Fixed Price APC,

Brand Drug means an originator/brand Drug Product listed or under consideration for listing on the ADBL,

Brand Price means the price of the Brand Drug published in the February ADBL in an Established IC Grouping or, if there is more than one originator/brand product in the Established IC Grouping, the Brand Price is the lowest published price of a Brand Drug in the Established IC Grouping,

Claim means a submission for reimbursement to the Plan for a Drug Product or Device,

Confirmed Price means a Confirmed Price in compliance with clauses 3, 4 and 5, and as submitted by the Manufacturer via the Price Confirmation **or as adjusted by the Minister pursuant to clauses 18(d), 23 or 25(b)**,

Device means a product approved by Health Canada as a device and listed or under consideration for listing by the Minister on the ADBL,

Drug Product means anything drug or drug related that is listed or under consideration for listing by the Minister on the ADBL,

Drug Program Act or **DPA** means the *Drug Program Act* of Alberta,

Effective Period means the Effective Period stated in the applicable APC Terms and Conditions,

Entry IC Drug means a Drug Product that is under consideration for listing in a New IC Grouping or Established IC Grouping,

Established IC Grouping means an IC Grouping that was established on or before February 1, 2023 and listed in the February ADBL,

February ADBL means the ADBL published by the Minister on or about February 1, 2023,

Fixed Price means the applicable Fixed Price as set out in the Fixed Pricing Rules,

Fixed Price APC Terms and Conditions means the Terms and Conditions outlined in a Fixed Price APC and includes the Signature Page as defined in such Terms and Conditions,

IC Drug means a Drug Product that is listed, or is under consideration for listing, as interchangeable with one or more Drug Products as determined by the Minister in accordance with the requirements relating to interchangeability in Section 1 of the ADBL,

IC Grouping means a category on the ADBL where there are two or more IC Drugs listed or under consideration for listing as part of one grouping on the ADBL as determined by the Minister,

Interim APC means an Interim Fixed Price APC or an Interim Non-Fixed Price APC,

Interim Fixed Price APC means an APC issued by the Minister for one or more Fixed Price Drug Products, or one or more categories or groupings of Fixed Price Drug Products during an Effective Period,

Interim Fixed Price APC Terms and Conditions means the terms and conditions outlined in an Interim Fixed Price APC,

Interim Non-Fixed Price APC means an APC issued by the Minister for one or more Non-Fixed Price Drug Products or Devices, or one or more categories or groupings of Non-Fixed Price Drug Products or Devices during an Effective Period,

Interim Non-Fixed Price APC Terms and Conditions means the terms and conditions outlined in an Interim Non-Fixed Price APC,

Least Cost Alternative Price or LCA Price means the maximum amount established by the Minister which will be paid by the Government of Alberta for a Drug Product in an Established IC Grouping or New IC Grouping for members of a Plan,

MAC Grouping means a grouping of Drug Products or Devices that have been listed on the ADBL and are subject to a MAC Price; a MAC Grouping may include a grouping of IC Drugs, in which case the grouping shall be treated as an Established IC Grouping,

Manufacturer means an entity that manufactures, sells or distributes a Drug Product or Device,

Market Exit Assessment Form: An assessment form provided through the Pan-Canadian Generic Initiative that identifies a newly established price of a Fixed Price Drug Product that may be adjusted pursuant to the conditions identified in clause 18,

Maximum Allowable Cost Price or MAC Price means the maximum amount established by the Minister that will be paid by the Government of Alberta for a Drug Product or Device in a MAC Grouping for members of a Plan,

Maximum Term means the Maximum Term stated in the applicable APC Terms and Conditions,

Minister means His Majesty the King in right of Alberta, as represented by the Minister of Health,

New IC Grouping means an IC Grouping that was established or may be established after February 1, 2023,

Non-Fixed Price means the applicable Non-Fixed Price as set out in the Non-Fixed Pricing Rules,

Non-Fixed Price APC Terms and Conditions means the Terms and Conditions outlined in a Non-Fixed Price APC and includes the Signature Page as defined in such Terms and Conditions,

Nutritional Product means a product categorized as a caloric agent once listed or under consideration for listing on the ADBL,

Patented Drug Product: Drug Products subject to the Non-Fixed Pricing Rules as well as subject to assessments under the PMPRB Guidelines.

Pan-Canadian Competitive Value Price Initiative for Generic Drugs or Pan-Canadian Generic Initiative is a collaboration of participating Canadian jurisdictions to establish the prices of generic Drug Products in accordance with the Pan-Canadian Generic Value Price Initiative which is established through the Pan-Canadian Generic Initiative Point of Entry process as further described in clause 18,

Pan-Canadian Select Molecule Price Initiative means the price-setting approach established by the Health Care Innovation Working Group of the Council of the Federation to set the price for select generic drug molecules in the Participating Jurisdictions as outlined in Appendix A of the Pan-Canadian Select Molecule Price Initiative Terms and Conditions,

Pan-Canadian Select Molecule Price Initiative Terms and Conditions means the Terms and Conditions outlined in Pan-Canadian Select Molecule Price Initiative APC and includes the Signature Page as defined in such Terms and Conditions,

Participating Jurisdiction has the same meaning as defined in the Pan-Canadian Select Molecule Price Initiative Terms and Conditions,

Plan means a plan or program for which the Government of Alberta provides benefits in respect of Drug Products or Devices listed on the ADBL,

Price Confirmation means the package of documents identified in an APC which must be completed and submitted in accordance with this Price Policy and the applicable APC Terms and Conditions,

Product Listing Agreement or PLA means a product listing agreement that is entered into or may be entered into by the Minister in respect of any Drug Product or Device in accordance with the Minister's Product Listing Agreement Policy, including any Drug Product or Device that is listed or under consideration for listing on the ADBL,

Product Listing Agreement Policy means any product listing agreement policy (including any processes related thereto) that may be published by the Minister from time to time.

ALBERTA PRICE CONFIRMATION (APC) FOR NON-FIXED PRICE, FIXED PRICE AND PAN-CANADIAN SELECT MOLECULE PRICE INITIATIVE DRUG PRODUCTS

1. The Minister may from time to time issue an Alberta Price Confirmation (APC) or an Interim APC, where a Manufacturer will be invited to submit a Price Confirmation, with one or more Confirmed Prices, in accordance with the applicable APC Terms and Conditions.

2. The Manufacturer must ensure that a Price Confirmation and a Confirmed Price submitted by a Manufacturer comply with:

    a. the Price Policy published at the time of an APC or Interim APC;

    b. the applicable APC Terms and Conditions issued for the Price Confirmation;

    c. the Pan-Canadian Generic Initiative, where applicable; and

    d. the Pan-Canadian Select Molecule Price Initiative, where applicable.

3. The Confirmed Price is the price that, if accepted by the Minister, shall be published in the ADBL.

4. For purposes of an APC and submitting a Price Confirmation, and subject to exceptions permitted by and approved under the Price Policy, the **Confirmed Price for a Drug Product or Device is**:

    a. **For a Drug Product subject to the Fixed Pricing Rules**, a price as set out in clause 18 of the Price Policy.

    b. **For a Drug Product or Device subject to the Non-Fixed Pricing Rules,** a price that is less than or equal to the Non-Fixed price (per unit of issue) as set out in clause 19 of the Price Policy.

5. In addition, **a Confirmed Price**:

    a. is applicable to a Drug Product or Device regardless of the package size for each Drug Product or Device;

    b. must not include the Goods and Services Tax (GST) or any other tax; and must not include any additional fees and/or charges; and

    c. For clarity, notwithstanding clause 5(b), Drug Products that are nutritional products that are subject to provincially mandated container recycling fees in Alberta may include recycling fees within their Confirmed Price.

6. The Minister may extend the duration of the Effective Period for a period, or periods, of time up to and including the last day of the Maximum Term.

7.

    a. The Manufacturer is responsible for ensuring that sufficient supply of a Drug Product or Device is available to the Alberta market prior to the acceptance of an APC, for which a Confirmed Price has been submitted, and is available for the Alberta market at the Confirmed Price for the duration of the Maximum Term.

b. If the Manufacturer anticipates that it may be unable to comply with the provisions of clause 7(a), the Manufacturer must advise Alberta Blue Cross immediately in writing via email to APCINQ@ab.bluecross.ca.

c. Where a Manufacturer is unable to supply a Drug Product or Device after the Drug Product or Device has been listed, the Manufacturer may be required to reimburse Alberta Health the difference in cost of covering a higher priced LCA Drug Product, the Brand Price or providing a temporary benefit, as described in the Supply Shortages policy in Section 1 of the ADBL, when one or more of the following criterion are met:

   i. Manufacturers of Entry IC Drug Product(s) or Non-Fixed Price Drug Product(s) under consideration for listing that have confirmed ability to supply the Alberta market through the following mechanisms:

      1. Letter confirming ability to supply the Alberta market as per the ADBL Submission Requirements located in Section 1 of the ADBL,

      2. Signing and returning the applicable Alberta Price Confirmation Signature Page, and

      3 The Minister has received confirmation that the Manufacturer's Pan-Canadian Generic Initiative price confirmation form has been accepted and the applicable tier has been established by the Pan-Canadian Generic Initiative.

   ii. Manufacturers of Drug Product(s) listed in a New IC or Established IC Grouping or currently listed Non-Fixed Drug Product(s) or Device(s) that have been confirmed as unable to supply by Alberta Blue Cross for at least six months.

d. Manufacturers of Drug Product(s) or Device(s) listed on the ADBL that fall under either clause 7(c)(i) or 7(c)(ii) will be granted the opportunity to provide rationale and documentation that the supply shortage of their Drug Product(s) or Device(s) was due to extraordinary events beyond the Manufacturers control. Based on the information provided, the Minister will consider whether reimbursement by the Manufacturer in accordance with clause 7(c) is required.

8. The Minister may consider a Confirmed Price and may accept none, one or more Confirmed Prices (with or without any request for an exception to the Fixed Pricing and Non-Fixed Pricing Rules (as applicable)) submitted in one or more Price Confirmations.

9. Notwithstanding the acceptance of a Confirmed Price, the Minister is not obligated to pay that price for members of a Plan, but may establish special or exceptional prices, including but not limited to establishing:

   a. an LCA Price,

   b. a MAC Price, or

   c. a special or exceptional price.

10. When considering a Confirmed Price for acceptance, and in determining whether to establish an LCA Price, a MAC Price, or a special or exceptional price, the Minister may consider any factor or criteria outlined in the ADBL, any matter permitted by the *Drug Program Act*, any matter arising from the Pan-Canadian Generic Initiative or the Pan-Canadian Select Molecule Price Initiative, or any matter that the Minister determines is in the public interest.

INTERIM APC

11. Notwithstanding the acceptance of a Confirmed Price by the Minister, in the event that:

    a. a new Drug Product or Device is being considered for listing in an Established IC Grouping, New IC Grouping or MAC Grouping;

    b. a Drug Product is being considered by the Pan-Canadian Generic Initiative or the Pan-Canadian Select Molecule Price Initiative;

    c. a Manufacturer submits a price reduction in accordance with clause 26 of this Price Policy;

    d. a Manufacturer transfers the authority to market a Drug Product or Device to another Manufacturer;

    e. a Manufacturer is required to adjust their Confirmed Price to comply with the Patented Medicine Prices Review Board (PMPRB) Guidelines[1]

    f. for any reason that the Minister determines that it is advisable to do so,

    the Minister may issue an Interim APC for one or more Drug Products or Devices, or one or more groupings of Drug Products or Devices.

12. If a Manufacturer submits a new Drug Product or Device submission for review and listing on the ADBL, and an Interim APC is issued, the Manufacturer must submit a Confirmed Price for that Drug Product or Device that:

    a. is equal to or less than the price as outlined in the Drug Product or Device submission, and

    b. does not exceed the prices permitted under this Price Policy,

    or the Drug Product or Device may not be listed or the listing of the Drug Product or Device may be delayed.

13.

    a. When a Pan-Canadian Select Molecule Price Initiative APC or Interim Fixed Price APC are issued, all Manufacturers who have a Fixed Price Drug Product listed in the affected

[1] PMPRB Guidelines can be found at: https://www.canada.ca/content/dam/pmprb-cepmb/documents/legislation/guidelines/PMPRB-Guidelines-en.pdf

Established IC Grouping, New IC Grouping or MAC Grouping will be required to submit a new Price Confirmation and Confirmed Price for the affected Fixed Price Drug Product in accordance with the Pan-Canadian Generic Initiative and the Pan-Canadian Select Molecule Price Initiative and the Fixed Pricing Rules as per clause 18 of this Price Policy. In the event that a new Confirmed Price for an affected Fixed Price Drug Product is not submitted or if the Confirmed Price for the affected Fixed Price Drug Product is greater than the price prescribed through the Pan-Canadian Generic Initiative, Pan-Canadian Select Molecule Price Initiative or the Fixed Pricing Rules then the affected Fixed Price Drug Product will be delisted.

b. Notwithstanding clause 13(a), when a Drug Product under consideration for listing is included in an Interim Fixed Price APC, and the Confirmed Price as per the Fixed Pricing Rules outlined in clause 18 of this Price Policy for the Drug Product under consideration for listing does not affect the established LCA price for the affected Established IC Grouping, New IC Grouping or MAC Grouping, only the Drug Product under consideration for listing will be required to provide a Confirmed Price through the Interim Fixed Price APC.

14. In the event the Minister issues an Interim APC, and one or more Confirmed Prices are accepted as a result of the Interim APC, the applicable APC Terms and Conditions supersede any previous APC Terms and Conditions for the affected Drug Products or Devices for the remainder of the Effective Period.

15. Publication of amended Confirmed Prices is at the discretion of the Minister.

16. Unless permitted in this Price Policy or by the Minister, a Confirmed Price may not exceed a Confirmed Price for a Drug Product or Device that has been submitted and approved by the Minister through a prior APC relating to such Drug Product or Device.

17. The provisions in this Price Policy that apply to an APC also apply to an Interim APC, and where the term APC is used in such clauses, it shall be deemed to read Interim APC in the case of an Interim APC.

FIXED PRICING RULES

18. The Fixed Pricing Rules apply to any Drug Product, other than a Brand Drug, that is listed or under consideration for listing on the ADBL.

    a. During an APC or Interim Fixed Price APC, for a Fixed Price Drug Product listed or under consideration for listing that is not subject to the Pan-Canadian Select Molecule Price Initiative, it is the Manufacturer's responsibility to submit a Confirmed Price that is less than or equal to the LCA Price of the most recently published ADBL, the price established through the Pan-Canadian Generic Initiative, or the price published in the February ADBL, whichever is lower.

    a.1. Notwithstanding clause 18(a), during an APC or Interim Fixed Price APC for a Fixed Price Drug Product that is not subject to the Pan-Canadian Select Molecule Price Initiative and is listed in an Established IC Grouping, the Minister may, in their sole discretion, provide an opportunity to Manufacturers of an affected Drug Product to submit a Confirmed Price that is either the current LCA Price or the price of their Drug Product most recently published in an ADBL, when:

        i. the LCA Price of the Established IC Grouping is lower than:

1. the affected Drug Product's price most recently published in an ADBL, or

2. the LCA Price published in the February ADBL, and

ii. the established LCA Price is not a result of pricing established through the Pan-Canadian Generic Initiative.

b. Where the Pan-Canadian Generic Initiative issues a Market Exit Assessment Form Manufacturers who have Drug Products that are in the same IC Grouping as the Drug Product identified in a Market Exit Assessment Form will receive a single opportunity to adjust the affected Drug Product's Confirmed Price to be equal to or less than the maximum price established through the Pan-Canadian Generic Initiative during an APC or Interim Fixed Price APC. Manufacturers are not required to adjust their current prices if current prices are equal or lower than the price identified on the Market Exit Assessment Form.

c. During an APC or Interim Fixed Price APC, Manufacturers submitting a Confirmed Price for a Fixed-Price Drug Product subject to the Pan-Canadian Select Molecule Price Initiative must submit a price equal to the price established by the Pan-Canadian Select Molecule Price Initiative.

d. **The Minister may decrease the price of a Fixed Price Drug Product(s) when a lower price than what is currently listed on the ADBL has been established through the Pan-Canadian Generic Initiative with or without issuing an APC or Interim APC and regardless of whether an Entry IC Drug is being added to the IC Grouping. Such price shall become the Confirmed Price.** If a Manufacturer does not agree with this rule they should not submit a Confirmed Price to an APC or initial Interim APC. Manufacturers who decline to submit a Confirmed Price through the APC or an initial Interim APC of the Effective Period for the affected Drug Products may not be listed on the ADBL. For the purpose of this clause, the "initial Interim APC" refers to the first interim APC in which an Entry IC Drug submits pricing in accordance with the Alberta Price Policy.

e. The Minister may defer the listing of an Entry IC Drug Product if a price has not been received by the Pan-Canadian Generic Initiative.[2]

f. The Minister may request written evidence from the Pan-Canadian Generic Initiative that the price has been submitted and accepted in accordance with the Pan-Canadian Generic Value Price Initiative Point of Entry process.

Additional information regarding the Pan-Canadian Generic Initiative and the Pan-Canadian Select Molecule Price Initiative may be found at:

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[2] In order to issue a Fixed Price APC Alberta Blue Cross and Alberta Health must receive a completed and approved manufacturers' Tiered Pricing Confirmation Form which establishes the appropriate price and tier from the Pan-Canadian Generic Initiative **at least two business days** prior to Alberta Blue Cross issuing a Fixed Price APC.

https://www.pcpacanada.ca/generic-drug-framework

Questions regarding the Pan-Canadian Generic Initiative or the Pan-Canadian Select Molecule Price Initiative can be directed to:

PCPAGenericsOffice@ontario.ca

NON-FIXED PRICING RULES

19. The Non-Fixed Pricing Rules apply to Brand Drugs and Devices.

    a. The Confirmed Price must be:

        i. less than or equal to the previous price of that Drug Product or Device listed on the February ADBL, or

        ii. the submitted price where that Drug Product or Device was not previously listed on the ADBL, or

        iii. the previous price of the Drug Product or Device listed on the February ADBL, plus an increase that is less than or equal to the current PMPRB CPI-Based Price-Adjustment Factors[3]. Notwithstanding CPI price adjustment, the maximum allowable price increase for a Non-Fixed Price Drug Product or Device shall not exceed 5 per cent above the price in the February ADBL.

            1. The Confirmed Price must be less than or equal to 5 per cent higher than it was February 2023 AND must be less than or equal to 5 per cent higher than it was on the December 31, 2020 ADBL.

            2. Manufacturers requesting a price increase must review the published price their Drug Product was listed at on the December 2020 ADBL, the published price their Drug Product was listed at on the 2023 February ADBL; and the PMPRB Guidelines for allowable CPI increases for 2023. If the Non-Fixed Priced Drug Product or Device was not listed on the December 2020 ADBL, the Manufacturer will be required to determine the applicable PMPRB Guidelines CPI and the appropriate publication of the ADBL to determine allowable price increases for April 1, 2023.

    b. For Patented Drug Products, notwithstanding clause 19 (a), a Manufacturer of a Patented Drug Product shall notify Alberta Blue Cross immediately in writing via email to APCINQ@ab.bluecross.ca once a list price has been assessed and in effect for their Patented Drug Product through the PMPRB Guidelines process. Upon providing notification of this new price, the Confirmed Price must be less than or equal to the price established through the PMPRB Guidelines process for that Patented Drug Product.

    c. The Confirmed Price in respect of a Drug Product or Device may only increase from the price most recently published in an ADBL once per 12-month period for the APC, which shall be

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[3] https://www.canada.ca/en/patented-medicine-prices-review/services/are-you-patentee/cpi-adjustment-factors/2023-cpi-adjustment-factors.html

effective on or about April 1, 2023. Price increases will only be considered if a Manufacturer has entered into the Non-Fixed Price APC Terms and Conditions.

d. The Minister may provide the PMPRB with Confirmed Prices submitted through the APC to determine compliance with the PMPRB Guidelines.

EXCEPTIONS

20. Notwithstanding the Fixed Pricing Rules and the Non-Fixed Pricing Rules, a Manufacturer may request the Minister consider an exception to the Fixed Pricing Rules or the Non-Fixed Pricing Rules if one or more of the circumstances in clause 22 apply.

21. Notwithstanding anything else in this Price Policy, exception requests for Drug Products that are subject to either the Pan-Canadian Generic Initiative or the Pan-Canadian Select Molecule Price Initiative, both of which fall under the Fixed Pricing Rules, will not be considered under clause 20.

22. Where the Minister receives an exception request under clause 20 the Minister may, at their sole discretion, grant an exception if one or more of the following applies:

    a. for Drug Products or Devices with less than 250 Claims or an annual net cost of less than $50,000 for Plans, as calculated by the Minister and based on Claims experience information provided by Alberta Blue Cross relating to Plans, for the period of time that the Drug Product or Device was listed on the ADBL in the previous 12 months;

    b. where the manufacturing and distribution costs for a Drug Product or Device exceed the maximum price for such Drug Product or Device permitted by the Fixed Pricing Rules or the Non-Fixed Pricing Rules, as applicable:

        i. The Manufacturer must provide detailed written evidence of the following:

            1. The costs for each raw material separately, including that of the active pharmaceutical ingredient,

            2. The cost of manufacturing (excluding costs of raw materials),

            3. Cost of distribution (including direct distribution fees paid to distributors but excluding all rebates and/or professional allowances), and

            4. Other costs, as applicable.

        ii. All costs must be stated per unit of issue;

        or,

    c. where exceptional circumstances exist.

        i. Exceptional circumstances include, but are not limited to, circumstances where, in the opinion of the Minister, significant patient safety or access concerns or significant increased costs to the Plans could result if the Drug Product or Device was not available on the ADBL. The Manufacturer must provide detailed written evidence outlining the exceptional circumstance;

ii. Exceptional circumstances do not include aligning with formulary pricing in other jurisdictions or to align with any PMPRB Guidelines other than the application described within the Alberta Price Policy.

23. Where an exception is requested, the maximum price increase which will be granted by the Minister is 5 per cent above the February ADBL price for that Drug Product or Device. **Manufacturers who are granted an exception, but have requested a price increase above 5 per cent will be listed at 5 per cent above the price listed on the February ADBL. Such price shall become the Confirmed Price.** For clarity, for Non-Fixed Price Drug Products or Devices the maximum 5 per cent price increase is inclusive of any PMPRB increase as per clause 19.

24. The Minister reserves the right to defer consideration of the exception and request such additional evidence and information in support of such request as the Minister deems appropriate.

25. a. If an exception is requested for a Drug Product or Device in an APC, but is not approved by the Minister, the Manufacturer will not be given another opportunity to submit a new Confirmed Price in respect of such Drug Product or Device, unless:

i. the Minister determines it is advisable to do so; or

ii. the Manufacturer follows the applicable Resubmission process referred to in Section 1 of the ADBL.

b. Notwithstanding clause 25(a), if an exception request for a Drug Product or Device is not approved by the Minister, the Minister may continue to list a Drug Product or Device that was listed on the ADBL at the time the exception request was made in accordance with the following rules:

i. Drug Products subject to the Fixed Pricing Rules will continue to be listed at the previous price of the Drug Product listed on the February ADBL. Such price shall become the Confirmed Price; and

ii. Drug Products or Devices subject to the Non-Fixed Pricing Rules will continue to be listed at the previous price of the Drug Product or Device listed on the February ADBL, plus an increase that is equal to the current allowable PMPRB CPI-Based Price-Adjustment Factors, up to a maximum of 5 per cent. Such price shall become the Confirmed Price.

PRICE REDUCTIONS

26. During an Effective Period, further price reduction requests for Drug Products or Devices listed on the ADBL will be considered as follows:

i. For Drug Products or Devices listed in an Established IC Grouping or MAC Grouping the proposed price reduction must be at least 5 per cent less than the LCA Price or MAC Price published at the time Alberta Blue Cross receives the proposed price reduction.

ii. For all other Non-Fixed Price Drug Products or Devices, by notifying the Minister by sending a written notice to Alberta Blue Cross.

iii. Price reductions will not be considered for IC Drug Products subject to the Pan-Canadian Select Molecule Price Initiative.

If accepted by the Minister, the Minister will issue an Interim APC for the Manufacturer to provide the reduced Confirmed Price. Establishment of a new LCA Price or MAC Price and publication of a reduced price is the Minister's sole discretion.

MINISTER'S AUTHORITY

27. Notwithstanding any other provision in this Price Policy, where one or more of the following occurs:

a. no Price Confirmation or Confirmed Price is submitted in respect of a Drug Product or Device;

b. there is a failure to issue an APC, or submit a Price Confirmation or Confirmed Price(s) in respect of a Drug Product or Device in accordance with the applicable APC Terms and Conditions;

c. there is a rejection or non-acceptance of all or part of an APC, Price Confirmation or Confirmed Price(s), or of a request for an exception to either the Fixed Pricing Rules or Non-Fixed Pricing Rules;

d. a Price Confirmation or a Confirmed Price of an IC Drug in an APC or an Interim APC is lower than the Confirmed price or the Price Confirmation of any other IC Drug Products in an IC Grouping;

e. there is a failure by the Manufacturer to comply with the ADBL Price Policy, the applicable APC Terms and Conditions and/or the Pan-Canadian Generic Initiative or the Pan-Canadian Select Molecule Price Initiative in respect of a Drug Product or Device listed or under consideration for listing on the ADBL;

f. the Minister considers that a PLA that is satisfactory to the Minister must be entered into prior to and/or as a condition of the listing, or continued listing, of a Drug Product or Device on the ADBL;

the Minister may do any one or more of the following:

i. cancel the listing of,

ii. modify the listing of,

iii. refuse to add to the ADBL,

iv. refuse to expedite the submission of,

v. cancel or modify the benefit payable for,

vi. modify or impose rules, terms, restrictions or conditions (including the execution of a PLA satisfactory to the Minister) relating to, or

vii. request reimbursement from a Manufacturer where the Minister has paid or reimbursed a claim for a Drug Product or Device that exceeds the Confirmed Price of the Drug Product or Device as a result of the Manufacturer's failure to comply with an APC and the ADBL Price Policy and on such repayment terms as may be determined by the Minister.

viii. take any other action the Minister considers appropriate

in relation to the affected Drug Product or Device for any period of time as deemed appropriate by the Minister.

28. Notwithstanding any other provision in this Price Policy, the Minister has and retains the sole right to determine all matters relating to the listing or continued listing of a Drug Product or Device on the ADBL, including (without limitation) the sole right to:

a. determine whether or not the Fixed Pricing Rules, the Non-Fixed Pricing Rules, the Pan-Canadian Generic Initiative, the Pan-Canadian Select Molecule Price Initiative, or any other rules apply to a Drug Product or Device,

b. determine whether or not a Drug Product is to be considered a Brand Drug for purposes of this Price Policy and an APC,

c. determine whether or not to extend the Effective Period of an APC pursuant to clause 6,

d. determine whether or not a PLA must be executed as a condition of the listing or continued listing of a Drug Product or Device on the ADBL,

e. make any decisions or take any steps to amend a published price, an LCA Price, a MAC Price, a special or exceptional price, the Price Policy, the Product Listing Agreement or Product Listing Agreement Policy, the ADBL or make any other adjustments the Minister considers advisable,

f. make any decisions, take any actions or steps, or do anything that is authorized by the *Drug Program Act*,

g. pursue, negotiate and enter into agreements with one or more Manufacturers, distributors or vendors, including (without limitation) a PLA or other contractual agreement,

h. make arrangements with other persons to provide access to Drug Products or Device for members of the Plans,

i. make any decisions, or take any actions or steps, or do anything that the Minister considers appropriate, or

j. terminate an APC, a Price Confirmation, or all or part of a Price Confirmation, or one or more Confirmed Prices, or the listing of any or all Drug Products or Devices on the ADBL, upon 10 days written notice to any affected Manufacturer, which notice is deemed to be given by the Minister and received by the Manufacturer upon (a) publication of the written notice on the ADBL website operated by Alberta Blue Cross, or (b) by sending the notice via fax to the last known fax number of the Manufacturer, and the method of notice is at the Minister's sole discretion,

in order to maintain the integrity of the ADBL, to ensure reasonable access to treatment for members of the Plans, or to serve the public interest.

29.

a. For further clarity, in all cases where the execution of a PLA in respect of a Drug Product or Device is required as a condition of the listing or continued listing of a Drug Product or Device on the ADBL, the provisions of the Product Listing Agreement or Product Listing Agreement Policy must be satisfied. Nothing in this Price Policy is intended to limit or override the application or any provisions of the Product Listing Agreement Policy. The requirements for listing or continued listing of a Drug Product or Device outlined in the ADBL, including (without limitation) this Price Policy, as well as the Product Listing Agreement or Product Listing Agreement Policy must be satisfied.

b. For clarity, where a PLA is terminated, the listing of any Drug Product or Device on the ADBL may be terminated in the manner set out in clause 28(j) at the Minister's sole discretion.

30. Subject to clause 28(e), where the Minister amends the Price Policy during an Effective Period, the Minister shall provide Manufacturers of Drug Products or Devices listed on the ADBL as at that date with 30 days' notice of such amendment, and the Minister may also issue an Interim APC in relation to any Drug Product or Device affected by such amendment.

31. The Minister reserves the right to pursue any remedies available to the Minister in the event of any non-compliance with, or any breach of, the Price Policy, or any applicable APC Terms and Conditions.

32.

a. The Minister, Alberta Blue Cross, and their respective officers, employees, and agents, are not liable for any actions, damages, claims, liabilities, costs, expenses, or losses in any way, including consequential, special, indirect, incidental, punitive or special damages, costs, expenses, or losses (including, without limitation, lost profits and opportunity costs) arising out of or relating to an APC, an Interim APC, any Price Confirmation, a Confirmed Price, the Pan-Canadian Generic Initiative, the Pan-Canadian Select Molecule Price Initiative, or the ADBL, even if the Minister or Alberta Blue Cross have been advised of the possibility of such damages beforehand. The provisions of this clause shall apply regardless of the form of action, damage, claim, liability, cost, expense, or loss, whether in contract, statute, tort (including, without limitation, negligence), or otherwise, and

b. In no event shall the maximum aggregate liability of the Minister, Alberta Blue Cross, and their respective officers, employees, and agents, for damages related to an APC, an Interim APC, a Price Confirmation, a Confirmed Price, the Pan-Canadian Generic Initiative, the Pan-Canadian Select Molecule Price Initiative, or the ADBL be greater than $25,000, or the Manufacturer's actual costs of preparing and submitting a Price Confirmation in response to an APC, whichever is less.

Least Cost Alternative (LCA) Price Policy

1. The Least Cost Alternative Price or LCA Price means the maximum amount established by the Minister which will be paid by the Government of Alberta for a Drug Product in an Established or New IC Grouping for members of a Plan.

2. Where the Minister establishes a LCA Price in Established and New IC Groupings the LCA Price:

   a. is the lowest unit per issue cost for a Drug Product in an IC Grouping that was submitted by the Manufacturer and accepted by the Minister in the most recent Alberta Price Confirmation.

   b. appears in bold type in the far right column of the ADBL.

   c. applies to all Drug Products in the applicable IC Grouping, unless the Minister determines that an exception should be made.

3. Notwithstanding clause 2 above, the LCA Price Policy does not apply to:

   - conjugated estrogens;
   - Devices; and
   - injectable Drug Products with different package sizes in an IC Grouping.

4. Subject to a Special Authorization being granted pursuant to clause 5 below, where a physician prescribes or a patient chooses an IC Drug that is priced higher than the LCA Price established by the Minister in the applicable IC Grouping, the patient will be responsible for any additional costs (being the difference in price between the higher-priced IC Drug and the LCA Price).

5. A physician may request Special Authorization if an IC Drug that is priced higher than the applicable LCA Price is essential in the care of a patient. For further information refer to the Special Authorization Guidelines clause of the ADBL.

Maximum Allowable (MAC) Price Policy

1. The MAC Price means the maximum amount established by the Minister which will be paid by the Government of Alberta for a Drug Product or Device in a MAC Grouping for members of a Plan.

2. A MAC Grouping means a grouping of Drug Products or Devices that have been listed on the ADBL or the List as being subject to a MAC Price; a MAC Grouping may include a grouping of IC Drugs, in which case the grouping shall be treated as an Established IC Grouping.

3. Where the Minister has established a MAC Price for a MAC Grouping, the MAC Price appears in ***bold italic*** type and is displayed in the ADBL in the second column from the right where two price columns are listed. A comment in ***bold italic*** type appears following a MAC Grouping to explain the basis for establishing the MAC Price.

4. The MAC Price Policy applies to the following MAC Groupings:

   - PTC 24:06.08

     Antilipemic Agents (HMG-COA Reductase Inhibitors)

   - PTC 24:28.08

     Calcium-Channel Blocking Agents (Dihydropyridines)

   - PTC 24:32.04
     Renin-Angiotensin-Aldosterone System Inhibitors
     (Angiotensin-Converting Enzyme Inhibitors)

   - PTC 28:08.04.92

     Selected Oral Modified-Release Dosage Forms of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

   - PTC 40:12

     Potassium Chloride (K+) 8 mEq Oral Sustained-Release Tablets
     Potassium Chloride (K+) 20 mEq Oral Tablet / Sustained-Release Tablets Potassium Chloride (K+)(CL-) 1.33 mEq / ml Oral Liquid

   - PTC 56:28:36

     Antiulcer Agents and Acid Suppressants (proton-pump inhibitors)

5. Subject to a Special Authorization being granted, where a physician prescribes or a patient chooses a Drug Product or Device in a MAC Grouping that is priced higher than a MAC Price established by the Minister for the applicable MAC Grouping, the patient will be responsible for any additional costs (being the difference in price between the higher-priced Drug Product or Device and the MAC Price).

6. A physician may request Special Authorization if the Drug Product or Device that is priced higher than the applicable MAC Price is essential in the care of a patient. For further information refer to the Special Authorization Guidelines clause of the ADBL.

Transitional Period Price Policy

1. With the exception of IC Drug Products affected by the Pan-Canadian Select Molecule Price Initiative, the Minister may establish a transitional period of up to 30 days to provide a temporary benefit or payment for a Drug Product or Device in accordance with the following:

    a. If a new IC Drug is added to the List which results in the establishment of a New IC Grouping, the Minister may temporarily pay the cost of the Brand Drug in that New IC Grouping for up to 30 days from the date the new IC Drug is listed;

    b. If a new IC Drug is added to the List in an Established IC Grouping at a lower price than the LCA Price , the Minister may temporarily pay the cost of the Drug Product that was the LCA Price prior to the addition of the new IC Drug for up to 30 days from the date the new IC Drug is listed;

    c. If a Drug Product or Device is discontinued or removed from the ADBL, the Minister may continue the affected Drug Product or Device as a temporary benefit for up to 30 days from the date of the notice that the Drug Product or Device is discontinued, or the date the listing was cancelled;

    d. Where the Transitional Period Price Policy is implemented because of a supply shortage, and an alternate Drug Product or Device is added to temporarily replace the Drug Product or Device in short supply:

        i. If the supply shortage is rectified in 30 days or less, no transitional period applies to the alternate Drug Product or Device;

        ii. If the supply shortage is rectified in more than 30 days, the alternate Drug Product or Device added and reimbursed under the Supply Shortages policy may continue to be reimbursed for up to 30 days after the supply shortage is rectified.

2. The Minister may make adjustments to the application of the Transitional Period Price Policy as required.