

Updates to the Alberta Drug Benefit List

Effective January 1, 2019



Inquiries should be directed to:

Pharmacy Services

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Website: <http://www.health.alberta.ca/services/drug-benefit-list.html>

Administered by Alberta Blue Cross
on behalf of Alberta Health.

The Drug Benefit List (DBL) is a list of drugs for which coverage may be provided to program participants. The DBL is not intended to be, and must not be used as a diagnostic or prescribing tool. Inclusion of a drug on the DBL does not mean or imply that the drug is fit or effective for any specific purpose. Prescribing professionals must always use their professional judgment and should refer to product monographs and any applicable practice guidelines when prescribing drugs. The product monograph contains information that may be required for the safe and effective use of the product.

Copies of the *Alberta Drug Benefit List* are available from Pharmacy Services, Alberta Blue Cross at the address shown above.

Binder and contents: **\$42.00** (\$40.00 + \$2.00 G.S.T.)

Contents only: **\$36.75** (\$35.00 + \$1.75 G.S.T.)

A cheque or money order must accompany the request for copies.

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Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization for patients covered under Alberta government-sponsored drug programs.

New Drug Product(s) Available by Special Authorization

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
OCALIVA 5 MG TABLET	OBETICHOLIC ACID	00002463121	ICP
OCALIVA 10 MG TABLET	OBETICHOLIC ACID	00002463148	ICP
RENFLEXIS 100 MG / VIAL INJECTION	INFLIXIMAB	00002470373	SSB
REVESTIVE 5 MG / VIAL INJECTION	TEDUGLUTIDE	00002445727	SHB

New Drug Product(s) Available by Step Therapy / Special Authorization

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
SYNJARDY 5 MG / 500 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456575	BOE
SYNJARDY 5 MG / 850 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456583	BOE
SYNJARDY 5 MG / 1000 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456591	BOE
SYNJARDY 12.5 MG / 500 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456605	BOE
SYNJARDY 12.5 MG / 850 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456613	BOE
SYNJARDY 12.5 MG / 1000 MG TABLET	EMPAGLIFLOZIN/ METFORMIN HCL	00002456621	BOE

Drug Product(s) with Changes to Criteria for Coverage

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
JARDIANCE 10 MG TABLET	EMPAGLIFLOZIN	00002443937	BOE
JARDIANCE 25 MG TABLET	EMPAGLIFLOZIN	00002443945	BOE

PART 3

Special Authorization

ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

EMPAGLIFLOZIN

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:

- 1) History of myocardial infarction (MI)
- 2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
- 3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
- 4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
- 5) History of ischemic or hemorrhagic stroke
- 6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective"

All requests for empagliflozin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

10 MG ORAL TABLET

00002443937 JARDIANCE BOE \$ 2.6726

25 MG ORAL TABLET

00002443945 JARDIANCE BOE \$ 2.6726

**ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

EMPAGLIFLOZIN/ METFORMIN HCL

The drug product(s) listed below are eligible for coverage via the step therapy/special authorization process.

"FIRST-LINE DRUG PRODUCT(S): METFORMIN

As add-on therapy for the treatment of Type 2 diabetes in patients with intolerance to and/or inadequate glycemic control on:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- a sulfonylurea, AND
- for whom insulin is not an option.

Or, for whom these products are contraindicated.

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes and established cardiovascular diseases who have an inadequate glycemic control, if the following criteria are met:

- a sufficient trial (i.e. a minimum of 6 months) of metformin, AND
- established cardiovascular disease* as defined in the EMPA-REG OUTCOME trial

* Established cardiovascular disease is defined on the basis of one of the following:

- 1) History of myocardial infarction (MI)
- 2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
- 3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months
- 4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
- 5) History of ischemic or hemorrhagic stroke
- 6) Occlusive peripheral artery disease

Special authorization may be granted for 24 months.

Note: If a claim for the Step therapy drug product is rejected, pharmacists can use their professional judgment to determine the appropriateness of using the intervention code(s) noted below to re-submit a claim. The pharmacist is responsible to document on the patient's record the rationale for using the second-line therapy drug.

- UP - First-line therapy ineffective
- UQ - First-line therapy not tolerated
- CA - Prior adverse reaction
- CB - Previous treatment failure
- CJ - Product is not effective"

All requests for empagliflozin+metformin must be completed using the DPP-4/SGLT2 Inhibitors Special Authorization Request Form (ABC 60012).

5 MG * 500 MG ORAL TABLET			
00002456575	SYNJARDY	BOE	\$ 1.3783
5 MG * 850 MG ORAL TABLET			
00002456583	SYNJARDY	BOE	\$ 1.3783
5 MG * 1,000 MG ORAL TABLET			
00002456591	SYNJARDY	BOE	\$ 1.3783
12.5 MG * 500 MG ORAL TABLET			
00002456605	SYNJARDY	BOE	\$ 1.3783
12.5 MG * 850 MG ORAL TABLET			
00002456613	SYNJARDY	BOE	\$ 1.3783
12.5 MG * 1,000 MG ORAL TABLET			
00002456621	SYNJARDY	BOE	\$ 1.3783

ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

INFLIXIMAB

100 MG / VIAL INJECTION

☒ 00002470373 RENFLEXIS SSB \$ 493.0000

***Effective January 1, 2019, all new Special Authorization requests for the treatment of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease or Ulcerative Colitis for infliximab naive patients will be assessed for coverage with Inflectra or Renflexis. Remicade will not be approved for new infliximab starts for patients with the indications stated above; however, coverage for Remicade will continue for patients who are currently well maintained on Remicade and are considered a 'responder' as defined in criteria.

Additionally, patients will not be permitted to switch between infliximab products, if the patient has been previously trialed on any infliximab product and deemed unresponsive to therapy.***

Rheumatoid Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for the reduction in signs and symptoms of severely active Rheumatoid Arthritis (RA) in adult patients (18 years of age or older) who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- Methotrexate with other disease modifying anti-rheumatic agent(s) (minimum 4 month trial) [e.g., methotrexate with hydroxychloroquine or methotrexate with sulfasalazine]; AND
- Leflunomide (minimum 10 week trial at 20 mg daily)

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 3 mg/kg, followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another (with the exception of anakinra) following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients will not be permitted to switch from anakinra to other biologic agents except under exceptional circumstances.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place]; AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 3 mg/kg dose every 8 weeks for a period of 12 months [Note: For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks]. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy

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INFLIXIMAB

as indicated by:

- confirmation of maintenance of ACR20, OR
- maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.

3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Rheumatoid Arthritis must be completed using the Abatacept/Adalimumab/Anakinra/Certolizumab/Etanercept/Golimumab/Infliximab/Tocilizumab/Tofacitinib for Rheumatoid Arthritis Special Authorization Request Form (ABC 60027).

Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease:

"Special authorization coverage may be approved for coverage of infliximab for the reduction in signs and symptoms and induction and maintenance of clinical remission of Moderately to Severely Active Crohn's Disease and/or treatment of Fistulizing Crohn's Disease in patients who meet the following criteria:

- Infliximab must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross for infliximab for coverage for the treatment of Moderately to Severely Active Crohn's Disease and/or Fistulizing Crohn's Disease patients ('Specialist').
- Patients must be 18 years of age or older to be considered for coverage of infliximab.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients may be allowed to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy (both primary loss of response and secondary loss of response) or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

Prior to initiation of infliximab therapy for New Patients:

'New Patients' are patients who have never been treated with infliximab by any health care provider.

Moderately to Severely Active Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have a current Modified (without the physical exam) Harvey Bradshaw Index score of greater than or equal to 7 (New Patient's Baseline Score), AND be Refractory.

Refractory is defined as one or more of the following:

- 1) Serious adverse effects or reactions to the treatments specified below; OR
- 2) Contraindications (as defined in product monographs) to the treatments specified below; OR
- 3) Previous documented lack of effect at doses and for duration of all treatments specified below:
 - a) mesalamine: minimum of 3 grams/day for a minimum of 6 weeks; AND refractory to, or dependent on, glucocorticoids:
following at least one tapering dosing schedule of 40 mg/day, tapering by 5 mg each week to 20 mg, then tapering by 2.5 mg each week to zero, or similar;

[Note: Patients who have used the above treatments in combination will not be required to be challenged with individual treatments as monotherapy]

AND

b) Immunosuppressive therapy as follows:

- Azathioprine: minimum of 2 mg/kg/day for a minimum of 3 months; OR
- 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 3 months; OR
- Methotrexate: minimum of 15 mg/week for a minimum of 3 months.

OR

- Immunosuppressive therapy discontinued at less than 3 months due to serious adverse effects or

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reactions.

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Fistulizing Crohn's Disease:

Prior to initiation of infliximab therapy, New Patients must have actively draining perianal or enterocutaneous fistula(s) that have recurred or persisted despite:

- a) A course of an appropriate dose of antibiotic therapy (e.g. ciprofloxacin or metronidazole) for a minimum of 3 weeks; AND
- b) Immunosuppressive therapy:
 - Azathioprine: minimum of 2 mg/kg/day for a minimum of 6 weeks; OR
 - 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 6 weeks; OR
 - Immunosuppressive therapy discontinued at less than 6 weeks due to serious adverse effects or reactions.

[Note: Patients who have used the above treatments in combination for the treatment of Fistulizing Crohn's will not be required to be challenged with individual treatments as monotherapy]

Applications for coverage must include information regarding the dosages and duration of trial of each treatment the patient received, a description of any adverse effects, reactions, contraindications and/or lack of effect, as well as any other information requested by Alberta Blue Cross.

Coverage Criteria for Moderately to Severely Active Crohn's Disease AND/OR Fistulizing Crohn's Disease

- New Patients must meet the criteria above prior to being considered for approval.
- All approvals are also subject to the following applicable criteria.

Induction Dosing for New Patients:

- Coverage for Induction Dosing may only be approved for New Patients (those who have never been treated with infliximab by any health care provider).
- 'Induction Dosing' means a maximum of one 5 mg/kg dose of infliximab per New Patient at each 0, 2 and 6 weeks (for a maximum total of three doses).
- New Patients are eligible to receive Induction Dosing only once, after which time the Maintenance Dosing for New Patients and Continued Coverage for Maintenance Dosing criteria will apply.

Maintenance Dosing:

'Maintenance Dosing' means one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months to:

- New Patients following the completion of Induction Dosing; OR
- Existing Patients, who are patients that are being treated, or have previously been treated, with infliximab.

Maintenance Dosing for New Patients after Completion of Induction Dosing:

- The New Patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of Induction Dosing to determine response by obtaining a Modified Harvey Bradshaw Index score for patients with Moderately to Severely Active Crohn's Disease and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND
- The Specialist must confirm the Modified Harvey Bradshaw Index score shows a decrease from the New Patient's Baseline Score of greater than or equal to 3 points for patients with Moderately to Severely Active Crohn's and/or confirm closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

Maintenance Dosing for Existing Patients:

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- The patient must be assessed by a Specialist at least 4 to 8 weeks after the day the last dose of infliximab was administered to the patient and prior to administration of the next dose to obtain: a Modified Harvey Bradshaw Index Score (Existing Patient's Baseline Score) for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- these measures must be provided to Alberta Blue Cross for assessment for continued coverage for maintenance dosing.

(For existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for existing patients with Fistulizing Crohn's who respond then lose their response, the dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)

Continued Coverage for Maintenance Dosing:

Continued coverage may be considered for one 5 mg/kg dose of infliximab per patient provided no more often than every 8 weeks for a period of 12 months, if the following criteria are met at the end of each 12 month period:

- The New Patient or the Existing Patient must be assessed by a Specialist at least 4 to 6 weeks after the day the last dose of infliximab was administered to the patient and prior to the administration of the next dose to obtain a Modified Harvey Bradshaw Index Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; AND

- For New Patients: The Specialist must confirm that the patient has maintained a greater than or equal to 3 point decrease from the New Patient's Baseline Score for Moderately to Severely Active Crohn's and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's; OR

- For Existing Patients: The Specialist must confirm that the patient has maintained the Existing Patient's Baseline Score and/or closure of individual fistulas as evidenced by no or minimal fistula drainage despite gentle finger compression of fistulas that were draining at baseline for Fistulizing Crohn's.

(For new and existing patients with Moderately to Severely Active Crohn's Disease with an incomplete response or for new and existing patients with Fistulizing Crohn's who respond then lose their response, the maintenance dose may be adjusted to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose.)"

All requests (including renewal requests) for infliximab for Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease must be completed using the Adalimumab/Vedolizumab for Crohn's/Infliximab for Crohn's/Fistulizing Crohn's Disease Special Authorization Request Form (ABC 60031).

Ankylosing Spondylitis:

"Special authorization coverage may be provided for the reduction in the signs and symptoms and improvement in physical function of severely active Ankylosing Spondylitis, as defined by the Modified New York criteria for Ankylosing Spondylitis, in adult patients (18 years of age or older) who have active disease as demonstrated by:

- a BASDAI greater than or equal to 4 units, demonstrated on 2 occasions at least 8 weeks apart AND

- a Spinal Pain VAS of greater than or equal to 4 cm (on a 0-10 cm scale), demonstrated on 2 occasions at least 8 weeks apart AND

- who are refractory or intolerant to treatment with 2 or more NSAIDS each taken for a minimum of 4 weeks at maximum tolerated or recommended doses.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

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INFLIXIMAB

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
- 2) The RA Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Reduction of the BASDAI score by at least 50% of the pre-treatment value or by 2 or more units, AND
 - Reduction of the Spinal Pain VAS by 2 cm or more.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose of infliximab every 6 to 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by an RA Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

All requests (including renewal requests) for infliximab for Ankylosing Spondylitis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Ankylosing Spondylitis Special Authorization Request Form (ABC 60028).

Psoriatic Arthritis:

"Special authorization coverage may be provided for use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (18 years of age or older) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory or intolerant to:

- Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who do not exhibit a clinical response to PO methotrexate or experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory; AND
- An adequate trial of another disease modifying anti-rheumatic agent(s) (minimum 4 month trial).

Special authorization coverage of this agent may be provided for use as monotherapy in adult patients for whom methotrexate is contraindicated and/or for those patients who have experienced serious adverse effects.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be initiated by a Specialist in Rheumatology ("RA Specialist").

- Initial coverage may be approved for three doses as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

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INFLIXIMAB

- 1) The patient must be assessed by an RA Specialist after the initial three doses to determine response.
 - 2) The RA Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - ACR20 OR an improvement of 1.2 units in the DAS28 score [reported to one (1) decimal place];AND
 - An improvement of 0.22 in HAQ score [reported to two (2) decimal places].
- It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above.

Following this assessment, continued coverage may be approved for one 5 mg/kg dose every 8 weeks, for a period of 12 months. Ongoing coverage may be considered if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by an RA Specialist to determine response;
- 2) The RA Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - Confirmation of maintenance of ACR20, or
 - Maintenance of a minimum improvement of 1.2 units in DAS28 score [reported to one (1) decimal place] from baseline.
- 3) A current HAQ score [reported to two (2) decimal places] must be included with all renewal requests.

It should be noted that the initial score for the DAS28 or HAQ score on record will be rounded to the correct number of decimal places as indicated above."

All requests (including renewal requests) for infliximab for Psoriatic Arthritis must be completed using the Adalimumab/Certolizumab/Etanercept/Golimumab/Infliximab/Secukinumab for Psoriatic Arthritis Special Authorization Request Form (ABC 60029).

Plaque Psoriasis:

- "Special authorization coverage may be provided for the reduction in signs and symptoms of severe, debilitating plaque psoriasis in patients who:
- Have a total PASI of 10 or more and a DLQI of more than 10, OR
 - Who have significant involvement of the face, palms of the hands, soles of the feet or genital region; AND
 - Who are refractory or intolerant to:
 - Methotrexate at 20 mg (PO, SC or IM) or greater total weekly dosage (15 mg or greater if patient is 65 years of age or older) for more than 12 weeks. Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory, OR
 - Cyclosporine (6 weeks treatment); AND
 - Phototherapy (unless restricted by geographic location)

Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered.

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

For coverage, this drug must be prescribed by a Specialist in Dermatology ("Dermatology Specialist").

- Initial coverage may be approved as follows: An initial dose of 5 mg/kg, followed by additional 5 mg/kg doses at 2 and 6 weeks after the first infusion.
- Patients will be limited to receiving one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

**ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

For continued coverage beyond three doses, the patient must meet all of the following criteria:

- 1) The patient must be assessed by a Dermatology Specialist after the initial three doses to determine response.
- 2) The Dermatology Specialist must confirm, in writing, that the patient is a 'responder' that meets the following criteria:
 - Greater than or equal to 75% reduction in PASI score, or
 - Greater than or equal to 50% reduction in PASI score AND improvement of greater than or equal to 5 points in the DLQI.

Following this assessment, continued coverage may be considered for one 5 mg/kg dose of infliximab every 8 weeks for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed by a Dermatology Specialist every 12 months and is confirmed to be continuing to respond to therapy by meeting criteria as outlined in (2) above."

PASI and DLQI scores are required for all requests for Plaque Psoriasis including those requests for patients that have significant involvement of the face, palms, soles of feet or genital region.

All requests (including renewal requests) for infliximab for Plaque Psoriasis must be completed using the Adalimumab/Etanercept/Infliximab/Ixekizumab/Secukinumab/Ustekinumab for Plaque Psoriasis Special Authorization Request Form (ABC 60030).

Ulcerative Colitis:

"Special authorization coverage may be provided for the reduction in signs and symptoms and induction and maintenance of clinical remission of Ulcerative Colitis in adult patients (18 years of age or older) with active disease (characterized by a partial Mayo score >4 prior to initiation of biologic therapy) and who are refractory or intolerant to:

- mesalamine: minimum of 4 grams/day for a minimum of 4 weeks

AND

- corticosteroids (failure to respond to prednisone 40 mg daily for 2 weeks, or; steroid dependent i.e. failure to taper off steroids without recurrence of disease or disease requiring a second dose of steroids within 12 months of previous dose).

'Refractory' is defined as lack of effect at the recommended doses and for duration of treatments specified above.

'Intolerant' is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs.

Immunosuppressive therapy as follows may also be initiated if in the clinician's judgment a trial is warranted:

- i) Azathioprine: minimum of 2 mg/kg/day for a minimum of 2 months; OR
- ii) 6-mercaptopurine: minimum of 1 mg/kg/day for a minimum of 2 months

For coverage, this drug must be prescribed by a Specialist in Gastroenterology or a physician appropriately trained by the University of Alberta or the University of Calgary and recognized as a prescriber by Alberta Blue Cross ('Specialist').

Initial coverage may be approved for three doses of 5 mg/kg of infliximab at 0, 2 and 6 weeks.

- Patients will be limited to receiving a one dose of infliximab per prescription at their pharmacy.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the first biologic agent if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For continued coverage beyond three doses, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist between weeks 10 and 14 after the initiation of therapy to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' that meets the following criteria:
 - a decrease in the partial Mayo score of greater than or equal to 2 points

**ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

INFLIXIMAB

Following this assessment, continued coverage may be approved for dose of 5 mg/kg every 8 weeks for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by a Specialist in Gastroenterology to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - a decrease in the partial Mayo score of greater than or equal to 2 points from the score prior to initiation of infliximab therapy

Note: For patients who showed a response to induction therapy then experienced secondary loss of response while on maintenance dosing with 5 mg/kg, the maintenance dose may be adjusted from 5 mg/kg to 10 mg/kg by making an additional special authorization request to Alberta Blue Cross for the increased dose."

All requests (including renewal requests) for infliximab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Vedolizumab for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

**ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS**

OBETICHOLIC ACID

"For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:

- I. A confirmed diagnosis of PBC, defined as:
- Positive antimitochondrial antibodies (AMA); or
 - Liver biopsy results consistent with PBC.

AND

- II.a. The patient has received ursodeoxycholic acid (UDCA) for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:
- alkaline phosphatase (ALP) greater than or equal to 1.67 x upper limit of normal (ULN) and/or
 - bilirubin > ULN and < 2 x ULN.

OR

- II.b. The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

AND

- III. Initiated by a gastroenterologist or hepatologist (or an internal medicine specialist with an interest in gastroenterology / hepatology on a case-by-case basis, in geographic areas where access to these specialities is not available).

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the patient continues to benefit from treatment with obeticholic acid as evidenced by:

- A reduction in the ALP level to less than 1.67 x ULN; or
- A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Continued coverage may be approved for up to 12 months."

All requests (including renewal requests) for obeticholic acid must be completed using the Obeticholic Acid Special Authorization Request Form (ABC 60065).

5 MG ORAL TABLET

00002463121	OCALIVA	ICP	\$	98.6301
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10 MG ORAL TABLET

00002463148	OCALIVA	ICP	\$	98.6301
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ALBERTA DRUG BENEFIT LIST UPDATE
CRITERIA FOR SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

TEDUGLUTIDE

"Special authorization coverage may be provided for the treatment of adult patients (18 years of age or older) with short bowel syndrome (SBS) if all of the following criteria are met:

- SBS is a result of major intestinal resection (e.g., due to injury, volvulus, vascular disease, cancer, Crohn's Disease), and
- Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months, and
- PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption, and
- PN frequency and volume have been stable for at least one month.

For coverage, the drug must be initiated and monitored by a specialist in gastroenterology or an internal medicine specialist with an interest in gastroenterology on a case-by-case basis, in geographic areas where access to this specialty is not available ('Specialist').

Initial coverage may be approved for up to 24 weeks of 0.05 mg/kg/day administered subcutaneously once daily.

- Patients will be limited to receiving a two week supply of teduglutide per prescription at their pharmacy.

For continued coverage beyond 24 weeks, the patient must meet the following criteria:

- 1) The patient must be assessed by the Specialist between weeks 20 and 24, after initiation of therapy to determine response.
- 2) The Specialist must confirm in writing that the patient is a 'responder' as demonstrated by:
 - at least a 20% reduction in weekly PN volume from baseline.

Following this assessment, continued coverage may be provided for 0.05 mg/kg/day administered subcutaneously once daily for a period of 12 months. Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- 1) The patient has been assessed by the Specialist to determine response;
- 2) The Specialist must confirm in writing that the patient has maintained a response to therapy as indicated by:
 - confirmation of maintenance of at least a 20% reduction in weekly PN volume from baseline."

5 MG / VIAL INJECTION

00002445727 REVESTIVE SHB \$ 904.0000
