

Updates to the Alberta Drug Benefit List

Effective October 1, 2024



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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.

Table of Contents

Special Authorization	1
■ New Drug Product(s) Available by Special Authorization.....	1
■ Drug Product(s) with Changes to Criteria for Coverage.....	1
Added Product(s).....	1
New Established Interchangeable (IC) Grouping(s).....	1
Least Cost Alternative (LCA) Price Change(s).....	2
Product(s) with a Price Change	2
Discontinued Listing(s).....	2
Product(s) Removed from the ADBL as Price Policy Requirements not Satisfied.....	3
Part 2 Drug Additions.....	2-1
Part 3 Special Authorization.....	3-1

Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization effective October 1, 2024 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>
OMVOH 100 MG / SYRINGE INJECTION	MIRIKIZUMAB	00002539853	LIL
OMVOH PEN 100 MG / SYRINGE INJECTION	MIRIKIZUMAB	00002539845	LIL
OMVOH 300 MG / VIAL INJECTION	MIRIKIZUMAB	00002539861	LIL

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>
AURO-TOFACITINIB 5 MG TABLET	TOFACITINIB CITRATE	00002530007	AUR
AURO-TOFACITINIB 10 MG TABLET	TOFACITINIB CITRATE	00002530015	AUR
JAMP TOFACITINIB 5 MG TABLET	TOFACITINIB CITRATE	00002522896	JPC
PMS-TOFACITINIB 5 MG TABLET	TOFACITINIB CITRATE	00002522799	PMS
TARO-TOFACITINIB 5 MG TABLET	TOFACITINIB CITRATE	00002511304	TAR
TARO-TOFACITINIB 10 MG TABLET	TOFACITINIB CITRATE	00002511312	TAR

Added Product(s)

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
JAMP AMOXI CLAV 40 MG / 5.7 MG / ML SUSPENSION	AMOXICILLIN TRIHYDRATE/ CLAVULANATE POTASSIUM	00002539411	JPC
JAMP AMOXI CLAV 80 MG / 11.4 MG / ML SUSPENSION	AMOXICILLIN TRIHYDRATE/ CLAVULANATE POTASSIUM	00002539446	JPC
JAMP IPRATROPIUM HFA 20 MCG / DOSE INHALATION METERED-DOSE AEROSOL	IPRATROPIUM BROMIDE	00002542587	JPC
M-DOXYCYCLINE 100 MG TABLET	DOXYCYCLINE HYCLATE	00002543478	MTR
NRA-BETAHISTINE 8 MG TABLET	BETAHISTINE DIHYDROCHLORIDE	00002544911	NRA
NRA-BETAHISTINE 16 MG TABLET	BETAHISTINE DIHYDROCHLORIDE	00002544938	NRA

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective November 1, 2024.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
AMOXICILLIN TRIHYDRATE/ CLAVULANATE POTASSIUM	40 MG / 5.7 MG / ML SUSPENSION	0.1373

New Established Interchangeable (IC) Grouping(s), continued

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
IPRATROPIUM BROMIDE	20 MCG / DOSE INHALATION METERED-DOSE AEROSOL	0.0767

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price decrease, will be effective November 1, 2024. Please review the online [Interactive Drug Benefit List](#) for further information.

<u>Generic Description</u>	<u>Strength / Form</u>	<u>New LCA Price</u>
AMOXICILLIN TRIHYDRATE/ CLAVULANATE POTASSIUM	80 MG / 11.4 MG / ML SUSPENSION	0.1591

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until October 31, 2024. For products within an established IC Grouping, the LCA price may apply.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
M-AMOXI CLAV 80 MG/11.4 MG/ML SUSPENSION	80 MG / 11.4 MG / ML SUSPENSION	00002530694	MTR

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturer(s). The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective October 1, 2024, the listed product(s) will no longer be a benefit and where applicable, will not be considered for coverage by Special Authorization. A transition period will be applied and as of November 1, 2024 claims will no longer pay for these product(s).

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
AUBAGIO 14 MG TABLET	TERIFLUNOMIDE	00002416328	GZM
PEDIAPRED 1 MG / ML LIQUID	PREDNISOLONE SODIUM PHOSPHATE	00002230619	SAV
SANDOZ-OXYCODONE ACET 5 MG / 325 MG TABLET	OXYCODONE HCL/ ACETAMINOPHEN	00002307898	SDZ
VITAMIN A ACID 0.025% TOPICAL GEL	TRETINOIN	00001926470	VCL

Product(s) Removed from the ADBL as Price Policy Requirements not Satisfied

The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective October 1, 2024, the listed product(s) will no longer be a benefit and will not be considered for coverage by special authorization. A transition period will be applied and, as of November 1, 2024 claims will no longer pay for these products.

<u>Trade Name / Strength / Form</u>	<u>Generic Description</u>	<u>DIN</u>	<u>MFR</u>
RIVA-LATANOPROST 0.005% OPHTHALMIC SOLUTION	LATANOPROST	00002341085	RIV

PART 2

Drug Additions

ALBERTA DRUG BENEFIT LIST UPDATE

ALLOPURINOL

100 MG ORAL TABLET				
0000402818	APO-ALLOPURINOL	APX	\$	0.0780
00002402769	APO-ALLOPURINOL	APX	\$	0.0780
00002396327	MAR-ALLOPURINOL	MAR	\$	0.0780
200 MG ORAL TABLET				
00000479799	APO-ALLOPURINOL	APX	\$	0.1300
00002402777	APO-ALLOPURINOL	APX	\$	0.1300
00002396335	MAR-ALLOPURINOL	MAR	\$	0.1300
300 MG ORAL TABLET				
00000402796	APO-ALLOPURINOL	APX	\$	0.2125
00002402785	APO-ALLOPURINOL	APX	\$	0.2125
00002396343	MAR-ALLOPURINOL	MAR	\$	0.2125

AMOXICILLIN TRIHYDRATE/ CLAVULANATE POTASSIUM

40 MG / ML (BASE) * 5.7 MG / ML (BASE) ORAL SUSPENSION				
00002539411	JAMP AMOXI CLAV	JPC	\$	0.1373
00002238831	CLAVULIN-200	GSK	\$	0.1652
80 MG / ML (BASE) * 11.4 MG / ML (BASE) ORAL SUSPENSION				
00002539446	JAMP AMOXI CLAV	JPC	\$	0.1591
00002530694	M-AMOXI CLAV	MTR	\$	0.1591
00002238830	CLAVULIN-400	GSK	\$	0.3206

BETAHISTINE DIHYDROCHLORIDE

8 MG ORAL TABLET				
00002449145	AURO-BETAHISTINE	AUR	\$	0.0637
00002519682	M-BETAHISTINE	MTR	\$	0.0637
00002538121	MINT-BETAHISTINE	MPI	\$	0.0637
00002544911	NRA-BETAHISTINE	NRA	\$	0.0637
00002280183	TEVA-BETAHISTINE	TEV	\$	0.0637
16 MG ORAL TABLET				
00002449153	AURO-BETAHISTINE	AUR	\$	0.1106
00002466449	BETAHISTINE	SNS	\$	0.1106
00002519690	M-BETAHISTINE	MTR	\$	0.1106
00002538148	MINT-BETAHISTINE	MPI	\$	0.1106
00002544938	NRA-BETAHISTINE	NRA	\$	0.1106
00002330210	PMS-BETAHISTINE	PMS	\$	0.1106
00002280191	TEVA-BETAHISTINE	TEV	\$	0.1106
00002243878	SERC	BGP	\$	0.5467

DOXYCYCLINE HYCLATE

100 MG (BASE) ORAL TABLET				
00000874256	APO-DOXY	APX	\$	0.4560
00002351242	DOXYCYCLINE	SNS	\$	0.4560
00002543478	M-DOXYCYCLINE	MTR	\$	0.4560
00002536250	PRZ-DOXYCYCLINE	PCI	\$	0.4560
00002158574	TEVA-DOXYCYCLINE	TEV	\$	0.4560

IPRATROPIUM BROMIDE

20 MCG / DOSE INHALATION METERED DOSE AEROSOL				
00002542587	JAMP IPRATROPIUM HFA	JPC	\$	0.0767
00002247686	ATROVENT HFA	BOE	\$	0.1024

PART 3

Special Authorization

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

MIRIKIZUMAB

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 a total of 6 doses of mirikizumab administered every 4 weeks: 3 doses of mirikizumab 300 mg intravenous (IV) followed by either 3 doses of mirikizumab 200 mg subcutaneous (SC) OR an additional 3 doses of mirikizumab 300 mg IV (for patients who do not have adequate therapeutic response at Week 12).

- Patients will be limited to receiving one dose of mirikizumab 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 the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist in Gastroenterology after the initial 6 doses 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

Following this assessment, continued coverage may be approved for a dose of 200 mg SC every 4 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 mirikizumab therapy."

All requests (including renewal requests) for mirikizumab for Ulcerative Colitis must be completed using the Adalimumab/Golimumab/Infliximab/Mirikizumab/Ozanimod/Tofacitinib/Upadacitinib/Vedolizumab

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

MIRIKIZUMAB

for Ulcerative Colitis Special Authorization Request Form (ABC 60008).

300 MG / VIAL INJECTION

00002539861 OMVOH LIL \$ 2536.1400

100 MG / SYR INJECTION SYRINGE

00002539853 OMVOH LIL \$ 1268.0700

00002539845 OMVOH (PEN) LIL \$ 1268.0700

TOFACITINIB CITRATE

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).

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 months as follows:
- Tofacitinib 5 mg tablet: one tablet twice daily.
- Tofacitinib 11 mg extended-release tablet: one tablet daily.
- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

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

- 1) The patient must be assessed by an RA Specialist after the initial three months 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 5 mg twice daily or 11 mg 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 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

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

TOFACITINIB CITRATE

rounded to the correct number of decimal places as indicated above.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent or other Janus kinase (JAK) inhibitors."

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

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 an initial dose of 10 mg twice daily for 8 weeks. As an interim measure, coverage will be provided for additional doses of 5 mg twice daily for 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist after 8 weeks but no longer than 12 weeks after treatment 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

Following this assessment, continued coverage may be approved for a dose of 5 mg twice 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 a Specialist in Gastroenterology to determine

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

TOFACITINIB CITRATE

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 tofacitinib therapy.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent, other Janus kinase (JAK) inhibitors or a sphingosine 1-phosphate receptor modulator."

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

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

5 MG (BASE)	ORAL	TABLET			
00002530007	AURO-	TOFACITINIB	AUR	\$	5.9897
00002522896	JAMP	TOFACITINIB	JPC	\$	5.9897
00002522799	PMS-	TOFACITINIB	PMS	\$	5.9897
00002511304	TARO-	TOFACITINIB	TAR	\$	5.9897
00002423898	XELJANZ		PFI	\$	24.7733

TOFACITINIB CITRATE

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 an initial dose of 10 mg twice daily for 8 weeks. As an interim measure, coverage will be provided for additional doses of 5 mg twice daily for 4 weeks, to allow time to determine whether the New Patient meets coverage criteria for Maintenance Dosing below.

- Patients will be limited to receiving a one-month supply of tofacitinib per prescription at their pharmacy.
- Patients will not be permitted to switch back to tofacitinib if they were deemed unresponsive to therapy.

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

- 1) The patient must be assessed by a Specialist after 8 weeks but no longer than 12 weeks after treatment 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

Following this assessment, continued coverage may be approved for a dose of 5 mg twice 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 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 tofacitinib therapy.

Coverage cannot be provided for tofacitinib when intended for use in combination with a biologic agent, other Janus kinase (JAK) inhibitors or a sphingosine 1-phosphate receptor modulator."

Note: For patients who showed a response to induction therapy then experienced

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

TOFACITINIB CITRATE

secondary loss of response while on maintenance dosing with 5 mg, the maintenance dose may be adjusted from 5 mg to 10 mg by making an additional special authorization request to Alberta Blue Cross for the increased dose.

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

10 MG (BASE)	ORAL TABLET			
00002530015	AURO-TOFACITINIB	AUR	\$	21.1718
00002511312	TARO-TOFACITINIB	TAR	\$	21.1718
00002480786	XELJANZ	PFI	\$	43.7833
