Updates to the Alberta Human Services Drug Benefit Supplement

Effective February 1, 2016

Alberta Human Services

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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.

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 Alberta Human Services.

New Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
DUAKLIR GENUAIR 400 MCG / 12 MCG INHALATION POWDER	ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE	00002439530	AZC

Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACCEL-CELECOXIB 100 MG CAPSULE	CELECOXIB	00002435632	ACP
ACCEL-CELECOXIB 200 MG CAPSULE	CELECOXIB	00002435640	ACP
FINASTERIDE 5 MG TABLET	FINASTERIDE	00002445077	SNS

Additional Brand(s) and/or Strength(s) of Drug Products Available by Step Therapy / Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
MYLAN-TOLTERODINE ER 2 MG EXTENDED-RELEASE CAPSULE	TOLTERODINE L-TARTRATE	00002404184	MYP
MYLAN-TOLTERODINE ER 4 MG EXTENDED-RELEASE CAPSULE	TOLTERODINE L-TARTRATE	00002404192	MYP
PMS-SOLIFENACIN 5 MG TABLET	SOLIFENACIN SUCCINATE	00002417723	PMS
PMS-SOLIFENACIN 10 MG TABLET	SOLIFENACIN SUCCINATE	00002417731	PMS
SANDOZ SOLIFENACIN 5 MG TABLET	SOLIFENACIN SUCCINATE	00002399032	SDZ
SANDOZ SOLIFENACIN 10 MG TABLET	SOLIFENACIN SUCCINATE	00002399040	SDZ

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACLASTA 5 MG / 100 ML INJECTION	ZOLEDRONIC ACID	00002269198	NOV
PROLIA 60 MG / ML INJECTION SYRINGE	DENOSUMAB	00002343541	AMG
TARO-ZOLEDRONIC ACID 5 MG / 100 ML INJECTION	ZOLEDRONIC ACID	00002415100	TAR

Drug Product(s) with Changes to Criteria for Coverage, continued

Trade Name / Strength / Form	Generic Description	DIN	MFR
ZOLEDRONIC ACID 5 MG / 100 ML INJECTION	ZOLEDRONIC ACID	00002422433	DRL
ZOLEDRONIC ACID 5 MG / 100 ML INJECTION	ZOLEDRONIC ACID	00002408082	TEV

Optional Special Authorization

The following drug product(s) will be considered for coverage by optional special authorization for patients covered under Alberta government-sponsored drug programs. Criteria for coverage of Alberta Human Services can be found in the February 1, 2016 Updates To the Alberta Human Services Drug Benefit Supplement.

Please refer to Section 3A of the online Alberta Drug Benefit List at https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec3a.pdf for further information regarding the Optional Special Authorization of Select Drug Products criteria and related forms.

Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Optional Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
AURO-MOXIFLOXACIN 400 MG TABLET	MOXIFLOXACIN HCL	00002432242	AUR
JAMP-MOXIFLOXACIN 400 MG TABLET	MOXIFLOXACIN HCL	00002443929	JPC
MAR-MOXIFLOXACIN 400 MG TABLET	MOXIFLOXACIN HCL	00002447053	MAR

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective March 1, 2016.

Generic Description	Strength / Form	New LCA Price
MOXIFLOXACIN HCL	400 MG TABLET	1.5230
TOLTERODINE L-TARTRATE	2 MG EXTENDED-RELEASE CAPSULE	1.4733
TOLTERODINE L-TARTRATE	4 MG EXTENDED-RELEASE CAPSULE	1.4733

Discontinued Listing(s)

Notification of discontinuation has been received from the manufacturers. The Alberta government-sponsored drug programs previously covered the following drug product(s). Effective February 1, 2016, 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 Feburary 29, 2016 claims will no longer pay for these product(s). Please note, for product(s) that were covered by Special Authorization, no transition period will be applied, and as of January 31, 2016, claims will no longer pay for these product(s).

Trade Name / Strength / Form	Generic Description	DIN	MFR
CIPROFLOXACIN 750 MG TABLET	CIPROFLOXACIN HCL	00002353334	SNS
RAN-ALENDRONATE 10 MG TABLET	ALENDRONATE SODIUM	00002384701	RAN
RATIO-RIVASTIGMINE 3 MG CAPSULE	RIVASTIGMINE HYDROGEN TARTRATE	00002311291	RPH
ZANAFLEX 4 MG TABLET	TIZANIDINE HCL	00002239170	PAL

PART 3

Special Authorization

ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE DIHYDRATE

"For the long-term, twice-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, in patients who meet the following criteria:

- Have moderate to severe COPD as defined by spirometry, AND
- Have an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist [LABA] or long-acting muscarinic antagonist [LAMA]).

Special authorization will be granted for six months."

This product is eligible for auto-renewal.

All requests for aclidinium bromide + formoterol fumarate dihydrate must be completed using the Long-Acting Fixed-Dose Combination Products for COPD Special Authorization Request Form (ABC 60025).

400 MCG / DOSE * 12 MCG / DOSE	INHALATION	METERED INHALATION POWDER		
00002439530	DUAKLIR GENUAIR	AZC	$	1.0000

CELECOXIB

"1) For patients who are at high risk of upper gastrointestinal (GI) complications due to a proven history of prior complicated GI events (e.g. GI perforation, obstruction or major bleeding) or

2) For patients who have a documented history of ulcers proven radiographically and/or endoscopically.

Special authorization for both criteria may be granted for 6 months."

All requests for celecoxib must be completed using the Celecoxib Special Authorization Request Form (ABC 31140).

The following product(s) are eligible for auto-renewal.

100 MG ORAL CAPSULE

00002435632	**ACCEL-CELECOXIB**	**ACP**	$	**0.1748**
00002420155	ACT CELECOXIB	APH	$	0.1776
00002418932	APO-CELECOXIB	APX	$	0.1776
00002429675	CELECOXIB	SIV	$	0.1776
00002436299	CELECOXIB	SNS	$	0.1776
00002291975	GD-CELECOXIB	GMD	$	0.1776
00002424533	JAMP-CELECOXIB	JPC	$	0.1776
00002420058	MAR-CELECOXIB	MAR	$	0.1776
00002412497	MINT-CELECOXIB	MPI	$	0.1776
00002423278	MYLAN-CELECOXIB	MYP	$	0.1776
00002355442	PMS-CELECOXIB	PMS	$	0.1776
00002412373	RAN-CELECOXIB	RAN	$	0.1776
00002321246	SANDOZ CELECOXIB	SDZ	$	0.1776
00002442639	SDZ CELECOXIB	SDZ	$	0.1776
00002288915	TEVA-CELECOXIB	TEV	$	0.1776
00002239941	CELEBREX	PFI	$	0.6992

200 MG ORAL CAPSULE

00002435640	**ACCEL-CELECOXIB**	**ACP**	$	**0.3497**
00002420163	ACT CELECOXIB	APH	$	0.3553
00002418940	APO-CELECOXIB	APX	$	0.3553
00002429683	CELECOXIB	SIV	$	0.3553
00002436302	CELECOXIB	SNS	$	0.3553
00002291983	GD-CELECOXIB	GMD	$	0.3553
00002424541	JAMP-CELECOXIB	JPC	$	0.3553
00002420066	MAR-CELECOXIB	MAR	$	0.3553
00002412500	MINT-CELECOXIB	MPI	$	0.3553
00002399881	MYLAN-CELECOXIB	MYP	$	0.3553
00002355450	PMS-CELECOXIB	PMS	$	0.3553
00002412381	RAN-CELECOXIB	RAN	$	0.3553
00002321254	SANDOZ CELECOXIB	SDZ	$	0.3553
00002442647	SDZ CELECOXIB	SDZ	$	0.3553
00002288923	TEVA-CELECOXIB	TEV	$	0.3553
00002239942	CELEBREX	PFI	$	1.3988

DENOSUMAB

Postmenopausal Osteoporosis:

"For the treatment of postmenopausal osteoporosis in women who have a high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, as demonstrated by at least two of the following:
- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

AND

at least one of the following:
1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),
OR
2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying,
OR
3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min),
OR
4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates,
OR
5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

The following product(s) are eligible for auto-renewal.

Osteoporosis in men:

"For the treatment of osteoporosis in men who have:
A high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture,
OR
A moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture;

AND

at least one of the following:
1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated),

DENOSUMAB

OR
2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying,
OR
3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance < 35 mL/min),
OR
4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates,
OR
5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.
-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, risedronate) when these medications are intended for use as combination therapy.
-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

The following product(s) are eligible for auto-renewal.

60 MG / SYR INJECTION SYRINGE			
00002343541	PROLIA	AMG	$ 351.5100

FINASTERIDE

"For the treatment of benign prostatic hyperplasia in patients who are poor surgical risks or who have enlarged prostates and have moderate to severe symptoms suggestive of obstruction.

Special authorization may be granted for 6 months."

Information is required regarding the medical condition(s) or circumstances by which this patient would be deemed a poor surgical risk.

All requests (including renewal requests) for finasteride must be completed using the Dutasteride/Finasteride Special Authorization Request Form (ABC 31257).

The following product(s) are eligible for auto-renewal.

5 MG ORAL TABLET

00002355043	**FINASTERIDE**	**AHI**	$	**0.4633**
00002354462	ACT FINASTERIDE	APH	$	0.5418
00002365383	APO-FINASTERIDE	APX	$	0.5418
00002405814	AURO-FINASTERIDE	AUR	$	0.5418
00002445077	FINASTERIDE	SNS	$	0.5418
00002357224	JAMP-FINASTERIDE	JPC	$	0.5418
00002389878	MINT-FINASTERIDE	MPI	$	0.5418
00002356058	MYLAN-FINASTERIDE	MYP	$	0.5418
00002310112	PMS-FINASTERIDE	PMS	$	0.5418
00002371820	RAN-FINASTERIDE	RAN	$	0.5418
00002322579	SANDOZ FINASTERIDE	SDZ	$	0.5418
00002348500	TEVA-FINASTERIDE	TEV	$	0.5418
00002428741	VAN-FINASTERIDE	VAN	$	0.5418
00002010909	PROSCAR	MFC	$	1.9920

SOLIFENACIN SUCCINATE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin.

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

5 MG ORAL TABLET				
00002422239	**ACT SOLIFENACIN**	**APH**	$	**0.4223**
00002417723	**PMS-SOLIFENACIN**	**PMS**	$	**0.4223**
00002399032	**SANDOZ SOLIFENACIN**	**SDZ**	$	**0.4223**
00002397900	**TEVA-SOLIFENACIN**	**TEV**	$	**0.4223**
00002277263	VESICARE	ASP	$	1.5135
10 MG ORAL TABLET				
00002422247	**ACT SOLIFENACIN**	**APH**	$	**0.4223**
00002417731	**PMS-SOLIFENACIN**	**PMS**	$	**0.4223**
00002399040	**SANDOZ SOLIFENACIN**	**SDZ**	$	**0.4223**
00002397919	**TEVA-SOLIFENACIN**	**TEV**	$	**0.4223**
00002277271	VESICARE	ASP	$	1.5135

TOLTERODINE L-TARTRATE

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

FIRST-LINE DRUG PRODUCT(S): OXYBUTYNIN

"For patients who are intolerant to oxybutynin."

"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

2 MG ORAL EXTENDED-RELEASE CAPSULE				
00002404184	**MYLAN-TOLTERODINE ER**	**MYP**	$	**1.4733**
00002244612	DETROL LA	PFI	$	1.9857
4 MG ORAL EXTENDED-RELEASE CAPSULE				
00002404192	**MYLAN-TOLTERODINE ER**	**MYP**	$	**1.4733**
00002244613	DETROL LA	PFI	$	1.9857

ZOLEDRONIC ACID

Osteoporosis:

"For the treatment of postmenopausal osteoporosis in women who have a high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture, as demonstrated by at least two of the following:

- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

AND

at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying;

OR

2) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate. Severe gastrointestinal intolerance is defined as manifested by weight loss or vomiting directly attributable to the oral bisphosphonates.

OR

3) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level).

Special Authorization may be granted for 12 months.

-Patients will be limited to receiving one dose of zoledronic acid per prescription at their pharmacy.

-Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe.

-Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/ml injection."

-This product is eligible for auto-renewal for the treatment of osteoporosis.

All requests for zoledronic acid for osteoporosis must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

Paget's Disease:

"For the treatment of Paget's disease. Special Authorization for this criterion may be granted for one dose per 12 month period."

"Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."

ZOLEDRONIC ACID

0.05 MG / ML INJECTION

00002415100	**TARO-ZOLEDRONIC ACID**	**TAR**	$	**3.3540**
00002408082	**ZOLEDRONIC ACID**	**TEV**	$	**3.3540**
00002422433	**ZOLEDRONIC ACID**	**DRL**	$	**3.3540**
00002269198	ACLASTA	NOV	$	6.7683

PART 3A

Optional Special Authorization

Criteria For Optional Special Authorization Of Select Drug Products

Patient claims for select quinolone prescriptions written by a non-designated prescriber will be subject to a first forgiveness rule, meaning the first claim will be paid. Subsequent claims for the same product (irrespective of strength, route and form) within a 90-day period would require the prescriber to apply for special authorization for coverage on the patient□s behalf.

MOXIFLOXACIN HCL

"To be prescribed according to ONE of the following criteria:

For the treatment of

1) Community acquired pneumonia after failure of first line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy; or

2) Community acquired pneumonia in patients with co-morbidities (asthma, lung cancer, COPD, diabetes, alcoholism, chronic renal or liver failure, CHF, chronic corticosteroid use, malnutrition or acute weight loss, hospitalization within previous 3 months, HIV/AIDS, smoking); or

3) Acute exacerbation of chronic bronchitis after failure of first and second line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy; or

4) Acute sinusitis after failure of first line therapy, as defined by clinical deterioration after 72 h of antibiotic therapy or lack of improvement after completion of antibiotic therapy, in patients with beta-lactam (penicillin and cephalosporin) allergy; or

5) For use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases."

All requests for Moxifloxacin HCl must be completed using the Select Quinolones Special Authorization Request Form (ABC 30966).

400 MG (BASE) ORAL TABLET				
00002432242	**AURO-MOXIFLOXACIN**	**AUR**	$	**1.5230**
00002443929	**JAMP-MOXIFLOXACIN**	**JPC**	$	**1.5230**
00002447053	**MAR-MOXIFLOXACIN**	**MAR**	$	**1.5230**
00002242965	AVELOX	BAI	$	6.0858