

# **SECTION 3A**

## Criteria for Optional Special Authorization of Select Drug Products

# CRITERIA FOR OPTIONAL SPECIAL AUTHORIZATION OF SELECT DRUG PRODUCTS

The drug products listed in this section may be considered for coverage by optional special authorization for patients covered under Alberta Health-sponsored drug programs. (For Alberta Human Services clients, the optional special authorization criteria for coverage can be found in the Criteria for Optional Special Authorization of Select Drug Products section of the *Alberta Human Services Drug Benefit Supplement*.)

## Criteria for Coverage

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Wording that appears within quotation marks (“ ”) in this section is the official optional special authorization criteria, as recommended by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics, and approved by the Minister of Health. Wording that is not enclosed in quotation marks outlines specific information required to interpret criteria, guidelines for submitting requests and/or information regarding conditions under which coverage cannot be provided.

## Role of the Prescribers

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In conjunction with the criteria, prescribers have two options by which patients may be eligible for coverage of these select optional special authorization drug products.

- 1) Prescribers can register to be a *designated prescriber*. Registration allows for patients to receive coverage of select drug products **without special authorization** as long as the prescription is written for one of the criteria for coverage set out in this section. Should a designated prescriber wish to prescribe one of the select drug products outside the coverage criteria, they may do so but must indicate this on the prescription; however, patients will not be eligible for payment under the Alberta government-sponsored program for such prescription and the patient may choose to receive the product at their expense. The registration form may be found on the previous page.
- 2) Prescribers who choose not to register will be considered *non-designated prescribers*. Such prescribers **will be required to apply for special authorization** on the patient's behalf.

## Registration for Designated Prescriber Status – Select Quinolone Antibiotics

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On the reverse is the official *Registration for Designated Prescriber Status – Select Quinolone Antibiotics* (ABC 60041).

- All requests to become a “Registered Designated Prescriber” must be submitted using the *Registration for Designated Prescriber Status – Select Quinolone Antibiotics* form only.
- **Photocopy this form and use as required.**
- Submit completed forms by FAX to Alberta Blue Cross:  
(780) 498-8384 in Edmonton and area  
1-877-828-4106 toll-free for all other areas

**Once your request has successfully transmitted, please do not mail or re-fax your request.**



ALBERTA GOVERNMENT SPONSORED DRUG BENEFIT PROGRAMS  
OPTIONAL SPECIAL AUTHORIZATION

**REGISTRATION FOR DESIGNATED PRESCRIBER STATUS**  
*for Alberta Drug Benefit List Claim Coverage*

**Select Quinolone Antibiotics**  
ciprofloxacin, levofloxacin, moxifloxacin

Please complete all sections of this form  
and return it by fax to Alberta Blue Cross

*Registrations will be accepted on an ongoing basis*

|  |            |         |              |             |
|--|------------|---------|--------------|-------------|
| PRESCRIBER LAST NAME   | FIRST NAME | INITIAL | OFFICE PHONE | FAX         |
| OFFICE ADDRESS   |            | CITY    | PROVINCE     | POSTAL CODE |
| COLLEGE OF PHYSICIANS AND SURGEONS<br>REGISTRATION NUMBER<br>OR PROFESSIONAL REGISTRATION NUMBER   |            |         |              |             |
| I have reviewed the criteria for coverage of select quinolone products and I agree to abide by and only prescribe in accordance with such criteria as updated from time to time in the Optional Special Authorization section of the <i>Alberta Drug Benefit List</i> .  |            |         |              |             |
| SIGNATURE OF PRESCRIBER (required) _____   |            |         | DATE _____   |             |
| The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009 - 108 Street, Edmonton AB T5J 3C5. |            |         |              |             |

**PLEASE RETURN YOUR COMPLETED REGISTRATION BY FAX TO 1-877-305-9911**



## 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.

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### CIPROFLOXACIN

"For the treatment of:

1) Respiratory Tract Infections:

- end stage COPD with or without bronchiectasis, where there has been documentation of previous *Pseudomonas aeruginosa* colonization/infection or
- pneumonic illness in cystic fibrosis; or

2) Genitourinary Tract Infections:

- urinary tract infections,
- prostatitis,
- prophylaxis of urinary tract surgical procedures or
- gonococcal infections; or

3) Skin and Soft Tissue/Bone and Joint Infections:

- malignant/invasive otitis externa,
- bone/joint infections due to gram negative organisms or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. diabetic foot infection, decubitus ulcers; or

4) Gastrointestinal Tract Infections:

- bacterial gastroenteritis where antimicrobial therapy is indicated,
- typhoid fever (enteric fever), or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. intra-abdominal infections; or

5) Other:

- prophylaxis of adult contacts of cases of invasive meningococcal disease,
- therapy/step-down therapy of hospital acquired gram negative infections,
- empiric therapy of febrile neutropenia in combination with other appropriate agents or
- exceptional case of allergy or intolerance to all other appropriate therapies as defined by relevant guidelines/references i.e. AMA CPGs or Bugs and Drugs.
- for use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases."

All requests for ciprofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

**100 MG / ML ORAL SUSPENSION**

00002237514

CIPRO

BAI

\$

0.5750

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

**CIPROFLOXACIN HCL**

"For the treatment of:

1) Respiratory Tract Infections:

- end stage COPD with or without bronchiectasis, where there has been documentation of previous *Pseudomonas aeruginosa* colonization/infection or
- pneumonic illness in cystic fibrosis; or

2) Genitourinary Tract Infections:

- urinary tract infections,
- prostatitis,
- prophylaxis of urinary tract surgical procedures or
- gonococcal infections; or

3) Skin and Soft Tissue/Bone and Joint Infections:

- malignant/invasive otitis externa,
- bone/joint infections due to gram negative organisms or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. diabetic foot infection, decubitus ulcers; or

4) Gastrointestinal Tract Infections:

- bacterial gastroenteritis where antimicrobial therapy is indicated,
- typhoid fever (enteric fever), or
- therapy/step-down therapy of polymicrobial infections in combination with clindamycin or metronidazole e.g. intra-abdominal infections; or

5) Other:

- prophylaxis of adult contacts of cases of invasive meningococcal disease,
- therapy/step-down therapy of hospital acquired gram negative infections,
- empiric therapy of febrile neutropenia in combination with other appropriate agents or
- exceptional case of allergy or intolerance to all other appropriate therapies as defined by relevant guidelines/references i.e. AMA CPGs or Bugs and Drugs.
- for use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases."

All requests for ciprofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

**250 MG (BASE) ORAL TABLET**

|                    |                             |            |           |               |
|--------------------|-----------------------------|------------|-----------|---------------|
| <b>00002247339</b> | <b>ACT CIPROFLOXACIN</b>    | <b>TEV</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002381907</b> | <b>AURO-CIPROFLOXACIN</b>   | <b>AUR</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002353318</b> | <b>CIPROFLOXACIN</b>        | <b>SNS</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002386119</b> | <b>CIPROFLOXACIN</b>        | <b>SIV</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002380358</b> | <b>JAMP-CIPROFLOXACIN</b>   | <b>JPC</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002379686</b> | <b>MAR-CIPROFLOXACIN</b>    | <b>MAR</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002423553</b> | <b>MINT-CIPROFLOX</b>       | <b>MPI</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002248437</b> | <b>PMS-CIPROFLOXACIN</b>    | <b>PMS</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002303728</b> | <b>RAN-CIPROFLOX</b>        | <b>RAN</b> | <b>\$</b> | <b>0.4454</b> |
| <b>00002248756</b> | <b>SANDOZ CIPROFLOXACIN</b> | <b>SDZ</b> | <b>\$</b> | <b>0.4454</b> |

**500 MG ORAL TABLET**

|                    |                             |            |           |               |
|--------------------|-----------------------------|------------|-----------|---------------|
| <b>00002247340</b> | <b>ACT CIPROFLOXACIN</b>    | <b>TEV</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002381923</b> | <b>AURO-CIPROFLOXACIN</b>   | <b>AUR</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002353326</b> | <b>CIPROFLOXACIN</b>        | <b>SNS</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002386127</b> | <b>CIPROFLOXACIN</b>        | <b>SIV</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002380366</b> | <b>JAMP-CIPROFLOXACIN</b>   | <b>JPC</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002379694</b> | <b>MAR-CIPROFLOXACIN</b>    | <b>MAR</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002492008</b> | <b>NRA-CIPROFLOXACIN</b>    | <b>NRA</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002248438</b> | <b>PMS-CIPROFLOXACIN</b>    | <b>PMS</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002303736</b> | <b>RAN-CIPROFLOX</b>        | <b>RAN</b> | <b>\$</b> | <b>0.5025</b> |
| <b>00002248757</b> | <b>SANDOZ CIPROFLOXACIN</b> | <b>SDZ</b> | <b>\$</b> | <b>0.5025</b> |

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

**CIPROFLOXACIN HCL**

750 MG (BASE) ORAL TABLET

|             |                      |     |    |        |
|-------------|----------------------|-----|----|--------|
| 00002247341 | ACT CIPROFLOXACIN    | TEV | \$ | 0.9201 |
| 00002380374 | JAMP-CIPROFLOXACIN   | JPC | \$ | 0.9201 |
| 00002379708 | MAR-CIPROFLOXACIN    | MAR | \$ | 0.9201 |
| 00002423588 | MINT-CIPROFLOX       | MPI | \$ | 0.9201 |
| 00002248439 | PMS-CIPROFLOXACIN    | PMS | \$ | 0.9201 |
| 00002303744 | RAN-CIPROFLOX        | RAN | \$ | 0.9201 |
| 00002248758 | SANDOZ CIPROFLOXACIN | SDZ | \$ | 0.9201 |

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

**LEVOFLOXACIN**

250 MG ORAL TABLET

|             |                     |     |    |        |
|-------------|---------------------|-----|----|--------|
| 00002315424 | ACT LEVOFLOXACIN    | TEV | \$ | 1.2038 |
| 00002284707 | APO-LEVOFLOXACIN    | APX | \$ | 1.2038 |
| 00002298635 | SANDOZ LEVOFLOXACIN | SDZ | \$ | 1.2038 |

"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 Levofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).



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

**LEVOFLOXACIN**

500 MG ORAL TABLET

|             |                     |     |    |        |
|-------------|---------------------|-----|----|--------|
| 00002315432 | ACT LEVOFLOXACIN    | TEV | \$ | 1.3718 |
| 00002284715 | APO-LEVOFLOXACIN    | APX | \$ | 1.3718 |
| 00002298643 | SANDOZ LEVOFLOXACIN | SDZ | \$ | 1.3718 |

"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 Levofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

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

**LEVOFLOXACIN**

750 MG ORAL TABLET

|                    |                            |            |           |               |
|--------------------|----------------------------|------------|-----------|---------------|
| <b>00002315440</b> | <b>ACT LEVOFLOXACIN</b>    | <b>TEV</b> | <b>\$</b> | <b>2.6604</b> |
| <b>00002325942</b> | <b>APO-LEVOFLOXACIN</b>    | <b>APX</b> | <b>\$</b> | <b>2.6604</b> |
| <b>00002298651</b> | <b>SANDOZ LEVOFLOXACIN</b> | <b>SDZ</b> | <b>\$</b> | <b>2.6604</b> |

"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 Levofloxacin must be completed using the Select Quinolones Special Authorization Request Form (ABC 60042).

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

**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 60042).

| 400 MG (BASE) ORAL TABLET |                     |     |    |        |
|---------------------------|---------------------|-----|----|--------|
| 00002478137               | AG-MOXIFLOXACIN     | AGP | \$ | 1.5230 |
| 00002404923               | APO-MOXIFLOXACIN    | APX | \$ | 1.5230 |
| 00002432242               | AURO-MOXIFLOXACIN   | AUR | \$ | 1.5230 |
| 00002443929               | JAMP-MOXIFLOXACIN   | JPC | \$ | 1.5230 |
| 00002447061               | JAMP-MOXIFLOXACIN   | JPC | \$ | 1.5230 |
| 00002472791               | M-MOXIFLOXACIN      | MTR | \$ | 1.5230 |
| 00002447053               | MAR-MOXIFLOXACIN    | MAR | \$ | 1.5230 |
| 00002457814               | MED-MOXIFLOXACIN    | GMP | \$ | 1.5230 |
| 00002520710               | MOXIFLOXACIN        | SNS | \$ | 1.5230 |
| 00002383381               | SANDOZ MOXIFLOXACIN | SDZ | \$ | 1.5230 |
| 00002375702               | TEVA-MOXIFLOXACIN   | TEV | \$ | 1.5230 |