ALBERTA BLUE CROSS®

ORAL VANCOMYCIN/FIDAXOMICIN SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed.

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

PATIENT INFORMATION

PATIENT LAST NAME	FIRST NAME	INITIAL

DATE OF BIRTH (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER

STREET ADDRESS	CITY	PROV	POSTAL CODE

COVERAGE TYPE

- ☐ Alberta Blue Cross
- ☐ Alberta Human Services
- ☐ Other

ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION

PRESCRIBER LAST NAME	FIRST NAME	INITIAL

STREET ADDRESS

CITY, PROVINCE

POSTAL CODE

PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION

☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other

REGISTRATION NUMBER

PHONE

FAX

FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED

Drug requested (check ONE only) ☐ Oral vancomycin (e.g. Vancocin)* ☐ Fidaxomicin (e.g. Dificid)

*Oral vancomycin is a benefit not requiring special authorization when prescribed by a specialist in infectious diseases or a designated prescriber.

Indicate diagnosis ☐ *Clostridium difficile* infection (CDI) ☐ Other (specify) _____

Oral vancomycin requests

1) Does the patient have severe CDI (i.e. WBC >15 x 10^9/L, serum creatinine ≥1.5 times baseline, hypotension or shock)? ☐ Yes ☐ No

2) Does the patient have documented or impending toxic megacolon? ☐ Yes ☐ No

Oral vancomycin re-treatment requests ONLY

3) Please indicate if treatment is requested for ☐ an early relapse OR ☐ a new CDI episode

Note: a CDI episode occurring ≥ 8 weeks after a previous episode with no intermittent recurrence of symptoms would be considered a new CDI episode.

Fidaxomicin requests

1) Is this the third or greater recurrence of CDI (i.e. fourth or greater episode of CDI)? ☐ Yes ☐ No

Fidaxomicin re-treatment requests ONLY

2) Please indicate if treatment is requested for ☐ an early relapse OR ☐ a new CDI episode

Note: a CDI episode occurring ≥ 8 weeks after a previous episode with no intermittent recurrence of symptoms would be considered a new CDI episode.

Previous medications utilized

Oral vancomycin and fidaxomicin requests (including initial and re-treatment requests)

1) ☐ Metronidazole has been used

a) Provide start date of most recent course (YYYY-MM-DD) _____

b) Specify response

☐ Clinical deterioration ☐ Documented failure as defined by no clinical improvement after five days of therapy

☐ Laboratory confirmed relapse of CDI with symptoms

→ Has the relapse occurred after two courses of metronidazole therapy? ☐ Yes ☐ No

☐ Intolerance or side effects ☐ Other (specify) _____

☐ Metronidazole has NOT been utilized. Please specify reason _____

Fidaxomicin requests ONLY (including initial and re-treatment requests)

2) ☐ Oral vancomycin has been used

a) Provide start date of most recent course (YYYY-MM-DD) _____

b) Specify response ☐ Failure ☐ Intolerance ☐ Other (specify) _____

☐ Oral vancomycin has NOT been used. Please specify reason _____

PRESCRIBER'S SIGNATURE	DATE

Please forward this request to

- **Alberta Blue Cross, Clinical Drug Services**
  10009-108 Street NW, Edmonton, Alberta T5J 3C5
- **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST

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.

ALBERTA BLUE CROSS®

ORAL VANCOMYCIN/FIDAXOMICIN SPECIAL AUTHORIZATION CRITERIA

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

Critiera for coverage

Oral vancomycin (e.g. Vancocin) Special Authorization criteria
"For the treatment of: 1) *Clostridium difficile* infection if there is clinical deterioration or documented failure on metronidazole therapy. Documented failure is defined as no clinical improvement after five days of therapy, or 2) Laboratory confirmed relapse of *Clostridium difficile* infection with symptoms after two courses of metronidazole therapy, or 3) Severe *Clostridium difficile* infection (defined as WBC >15 X 10exp9/L, serum creatinine >=1.5 times baseline, hypotension, or shock) or documented or impending toxic megacolon, or 4) *Clostridium difficile* infection if there is intolerance or side effects to metronidazole therapy. Special authorization for all criteria may be granted for three months."* *Special Authorization is only required when the prescriber prescribing the medication is not a specialist in infectious diseases or a designated prescriber.
Note: Oral vancomycin is also eligible via restricted benefit coverage when prescribed by a specialist in infectious diseases or a designated prescriber.
Fidaxomicin (e.g. Dificid) Special Authorization Criteria
For the treatment of: 1) *C. difficile* infection (CDI) where the patient has failed, or is intolerant of oral vancomycin*; or 2) Patients with third or greater recurrence of CDI (i.e. fourth or greater episode of CDI) *For CDI treatment protocol, please refer to vancomycin Special Authorization criteria. Note: - Fidaxomicin should not be used as an add-on to existing therapy (metronidazole or vancomycin). - Not studied in multiple recurrences or those with life-threatening or fulminant CDI, toxic megacolon or inflammatory bowel disease. Special authorization coverage for fidaxomicin will be provided for one treatment course (10 days) plus one additional treatment course for an early relapse occurring within eight weeks of the start of the most recent fidaxomicin course. New episode of CDI after eight weeks will require treatment with metronidazole and oral vancomycin* before fidaxomicin coverage may be considered.

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