FEBRUARY 2026

Special Authorization Guide

A Focus on the Newfoundland and Labrador Prescription Drug Program

A collaborative project between Memorial University's School of Pharmacy and the Family Practice Network (FPN) Less Paperwork Working Group.

TABLE OF CONTENTS

NLPDP SPECIAL AUTHORIZATION SUBMISSION GUIDELINE

ABOUT THE GUIDE

This project is a result of the Family Practice Network (FPN) Less Paperwork Working Group's idea to lessen the administrative burden. The FPN is grateful for this partnership with the School of Pharmacy to lead the development of this guide.

This how-to guide is an aid for submitting special authorization requests to the Newfoundland and Labrador Prescription Drug Program (NLPDP). As there is a variety of applications available for multiple conditions, medications, and services, the information contained in this guide is meant to provide supplemental guidance on completing special authorization forms. All questions and concerns about submissions, including inquiries about eligibility criteria and specific coverage, should be directed to the Pharmaceutical Services Division of the Newfoundland and Labrador Government. Of note, NLPDP was not involved in the development of this document.

Updates to NLPDP coverage occur continuously throughout the year; thus, elements of this document may not contain the most up-to-date information.

Annually, we will work together to incorporate feedback received from family physicians and pharmacists and add any newly suggested subject areas. Please provide any feedback on (a) how to make the guide more helpful and/or (b) suggested new diseases to cover to:
Danielle Beattie, Executive Assistant, FPNs at dbeattie@nlma.nl.ca

RELEVANT LINKS

Special Authorization Drug Products, Special Authorization Process: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/

Forms and Applications: https://www.gov.nl.ca/hcs/forms/

Standard Special Authorization Form: https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

NLPDP Coverage Status Searchable Database: https://www.health.gov.nl.ca/health/prescription/newformulary.asp

Provider Portal NLPDP Bulletins: https://nlpdp.bell.ca/

AUTHORS

Dr. Stephen Coombs
Project Lead

Dr. Mikaela Thorne
Content Contributor, Editor

Content Contributors

Dr. Stephanie Tracey
Dr. Brandi Marshall
Dr. Michael Coombs
Dr. Robyn O'Rielly
Dr. Deanne Goulding
Dr. Mahima Mishra
Dr. Rebecca Day
Dr. Caitlyn Coles
Dr. Sarah Hyslop
Ms. Hayley Collins

A special thanks goes to the pharmacists employed by the Newfoundland and Labrador Prescription Drug Program (NLPDP) for reviewing and providing feedback on this guidance document.

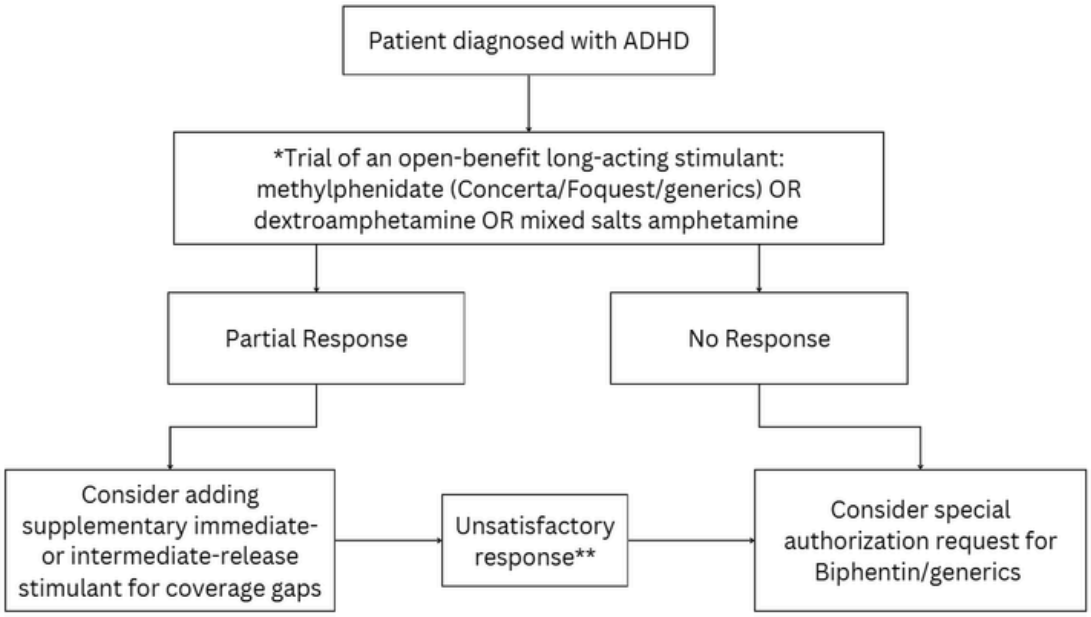
SPECIAL AUTHORIZATION PROCESS

NEWFOUNDLAND AND LABRADOR PRESCRIPTION DRUG PROGRAM

- Provides financial assistance to patients for payment of eligible prescription medications
- Five main plan options under the program:
  - Foundation Plan
  - 65 Plus Plan
  - Access Plan
  - Assurance Plan
  - Select Needs Plan
- Unless otherwise specified, the NLPDP Coverage Status Table outlines the benefit status for medications for each of the aforementioned plans. This table is updated once monthly and may not reflect very recent additions. It is helpful to monitor the 'New Drug Therapies' section of the NLPDP Bulletins for very recent additions.
- If a medication is listed as an open benefit*, it will automatically be covered under NLPDP and no special authorization application is required.
  - Limitations may apply to open benefit medications (e.g., an open-benefit medication may be limited to Children, Seniors, and Social Development beneficiaries).
  - The best way to find if a medication has limitations is to use the search tool that can be found on the Health and Community Services website.
- Any medications on this table listed as SPEC AUTH will require an application to be submitted prior to coverage being granted - patients must meet specified criteria before the drug can be considered.

ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

COVERAGE ALGORITHM: VYVANSE OR BIPHENTIN



*: a 3–4-week trial with stimulants is reasonable, although improvement of core ADHD symptoms is often observed in the first week of therapy.

**: Unsatisfactory response includes poor symptom control, side effects, administrative barriers, or societal barriers

TIPS

- Use the standard special authorization form.
- Available products (*in alphabetical order; those italicized are special authorization with NLPDP*):
  - Adderall XR & generics (mixed salts amphetamine extended release)
  - *Biphentin & generics* (methlphenidate controlled release)
  - Concerta & generics (methylphenidate extended release)
  - Dexedrine & generics (dextroamphetamine)
  - Dexedrine Spansules & generics (dextroamphetamine sustained release)
  - Foquest & generics (methylphenidate controlled release)
  - Ritalin & generics (methylphenidate)
  - Vyvanse & generics (lisdexamfetamine)
  - *Vyvanse chewable & generics (lisdexamfetamine)*
- Maximum dose of Biphentin covered is 80mg. Maximum dose of Vyvanse covered is 60mg.
- Reimbursement will not be considered for Biphentin and/or Vyvanse concurrently with methylphenidate (IR or SR) or dextroamphetamine (IR or SR formulation).

Considerations for dosage forms:

- Vyvanse is available in chewable tablet form; fill out the standard special authorization form.
- Adderall, Biphentin, and Dexedrine capsules (including generics) may be opened and sprinkled on soft foods. Check individual product monographs for stability and suitability of food choice.
- Immediate release stimulants: Dexedrine (dextroamphetamine IR) and Ritalin (methylphenidate IR).
- Intermediate release stimulants: methylphenidate SR and dextroamphetamine SR spansules.

NLPDP CRITERIA FOR BIPHENTIN

For treatment of attention deficit hyperactivity disorder (ADHD) in patients who:

- have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers, **AND**
- have been tried on extended-release methylphenidate (Concerta/Foquest and/or generics), dexamphetamine or mixed salts amphetamine with unsatisfactory results after an adequate trial of 3-4 weeks.

The most common adverse effects of stimulants are increased heart rate and blood pressure, GI upset, appetite suppression, anxiety, irritability, and insomnia.

Monitor during therapy:

- height/weight in children
- new mood, anxiety, substance use disorder, psychotic, or manic symptoms
- suicidal behaviour or ideation
- new or worsening aggressive behaviour
- sleep
- appetite
- irritability, mood swings

EVIDENCE FOR USE

The CADDRA 2018 guidelines recommend long-acting stimulants as first-line therapy for ADHD. Long-acting formulations of mixed salts amphetamine (Adderall XR), methylphenidate (Biphentin and Concerta) and lisdexamfetamine (Vyvanse) have a duration of action of 8-14 hours and are as effective as appropriately dosed shorter-acting stimulants.
Advantages of these long-acting products include single daily dosing, potential for improved adherence, avoidance of the need for medication administration at school, decreased abuse potential and decreased risk of rebound hyperactivity.

RENAL DOSING CONSIDERATIONS

Biphentin

- Adult and Pediatric
  - No dosage adjustments provided in manufacturer's labeling. Biphentin has not been studied in renal impairment. It does however undergo extensive metabolism to a renally eliminated metabolite.

Vyvanse

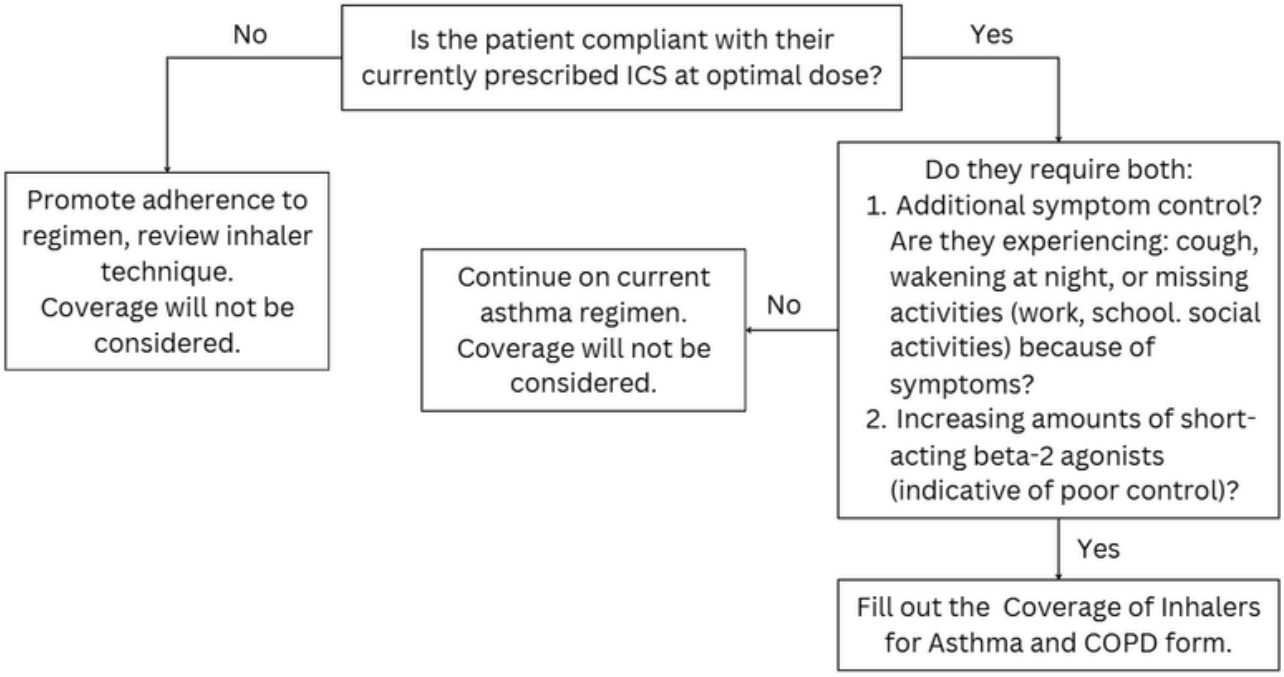
- Adult and Pediatric
  - GFR 15 to <30 mL/min/1.73 m^2 : maximum daily dose 50 mg
  - GFR <15 mL/min/1.73 m^2 : maximum daily dose 30 mg
  - Hemodialysis: maximum daily dose 30 mg; lisdexamfetamine and dextroamphetamine are not dialyzable

REFERENCES

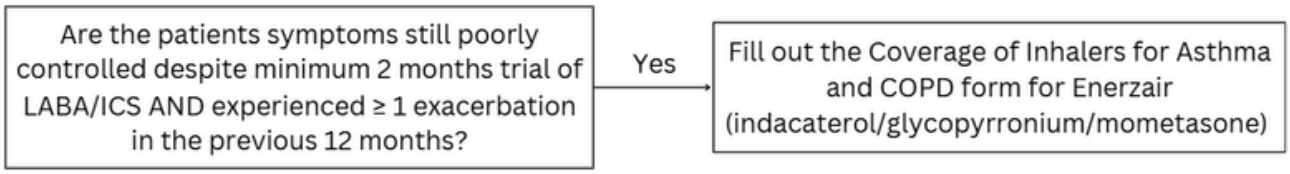
1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2022. Available from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/
2. Virani A. Attention-Deficit Hyperactivity Disorder. In: CPS Full Access [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2022 [updated April 2021; cited 2022 February 14]. Available from: https://www-myrxtx-ca.qe2a-proxy.mun.ca/search
3. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2020 Aug 11; cited 2023 Apr 3]. Biphentin [Product Monograph]. Available from http://www.myrxtx.ca.
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2020 Jul 21; cited 2023 Apr 3]. Vyvanse [Product Monograph]. Available from http://www.myrxtx.ca.

ASTHMA

COVERAGE ALGORITHM: COMBINATION ICS-LABA INHALED THERAPY (ADVAIR/BREO ELLIPTA/SYMBICORT/ZENHALE)



COVERAGE ALGORITHM: COMBINATION LABA/LAMA/ICS INHALED THERAPY (ENERZAIR)



TIPS

- Use the Coverage of Inhalers for Asthma and COPD form.
- Inhaled corticosteroids (*in alphabetical order; all open benefit under NLPDP*):
  - Alvesco MDI (ciclesonide)
  - Asmanex twisthaler (mometasone furoate)
  - Flovent MDI/Diskus (fluticasone propionate) & generics
  - Pulmicort turbuhaler (budesonide)
  - Qvar MDI (beclomethasone)
- Short-acting beta2-agonists (*in alphabetical order; all open benefit under NLPDP*):
  - Bricanyl turbuhaler (terbutaline)
  - Ventolin MDI (salbutamol) & generics
- Oral therapies:
  - Singulair (montelukast) & generics (*open benefit under NLPDP*)

NLPDP CRITERIA FOR ICS/LABA

Advair (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/formoterol), Zenhale (mometasone/formoterol)

Reversible Obstructive Airway Disease: For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta2-agonists, indicative of poor control (e.g., SABA reliever use more than twice/week as per GINA guidelines)

Treatment should be initiated and adjusted based on patient response and symptom control. A trial period of 2-3 months post initiation of optimal ICS and SABA is typically required before granting coverage for an ICS/LABA combination.

Recommendations for initial treatment of asthma in adults and adolescents:

Presenting Symptoms	Preferred Initial Treatment	Alternative Initial Treatment
Infrequent symptoms (e.g., 1-2 days/week or less)	As needed low dose ICS-formoterol (Symbicort or Zenhale)	Low dose ICS taken whenever SABA is taken (in combination or as separate inhalers)
Asthma symptoms less than 3-5 days/week, with normal or mildly reduced lung function	As needed low dose ICS-formoterol (Symbicort or Zenhale)	Low dose ICS with PRN SABA
Asthma symptoms during most days (e.g., 4-5 days/week or more) or waking due to asthma once a week or more or low lung function	Low dose ICS-formoterol maintenance and reliever therapy (Symbicort or Zenhale)	Low dose ICS-LABA plus PRN SABA/PRN ICS-SABA **OR** Medium dose ICS plus PRN SABA/PRN ICS-SABA
Daily asthma symptoms, waking at night with asthma once a week or more, with low lung function	Medium dose ICS-formoterol maintenance and reliever therapy	Medium or high dose ICS-LABA plus PRN SABA/PRN ICS-SABA

Recommendations for initial treatment of asthma in children aged 6-11 years:

Presenting Symptoms	Preferred Initial Treatment
Infrequent symptoms (e.g., 1-2 days/week or less)	Low-dose ICS taken whenever SABA is taken. Other options include daily maintenance low-dose ICS with PRN SABA
Asthma symptoms 2-5 days/week	Low dose ICS with PRN SABA Other options include: PO leukotriene receptor antagonists (LTRA), or ICS used whenever SABA is used
Asthma symptoms most days (e.g., 4-5 days/week) or waking due to asthma once a week or more	Low dose ICS-LABA with PRN SABA or Medium dose ICS with PRN SABA or Very low dose ICS-formoterol maintenance and reliever Other options include: low dose ICS with daily PO LTRA, with PRN SABA
Daily asthma symptoms, waking at night once or more a week, and low lung function	SMedium dose ICS-LABA plus PRN SABA or Low dose ICS-formoterol maintenance and reliever

ENERZAIR BREEZHALER (INDACATEROL/GLYCOPYRRONIUM/MOMETASONE)

Patients who have inadequately controlled asthma after a two month trial with a medium or high dose inhaled corticosteroid (ICS) and a long-acting beta-2 agonist (LABA) AND have experienced one or more asthma exacerbations in the previous 12 months will qualify for triple therapy for asthma with Enerzair (indacaterol/glycopyrronium/mometasone) Breezhaler.

EVIDENCE FOR USE

According to current evidence-based literature and guidelines, goals of therapy for those with asthma include achieving good symptom control, reducing limitations in day-to-day activities, and minimizing the risk of asthma-related mortality, exacerbations, persistent airflow limitations, and side effects of treatment. It is also imperative to discuss the patient's own goals regarding their asthma and their expectations of treatment. Additionally, decisions regarding treatment must take into consideration individual patient characteristics, patient preference, and practical issues such as inhaler technique and cost.

The GINA 2021 guidelines provide the following recommendations for symptom control and risk reduction for adults and adolescents:

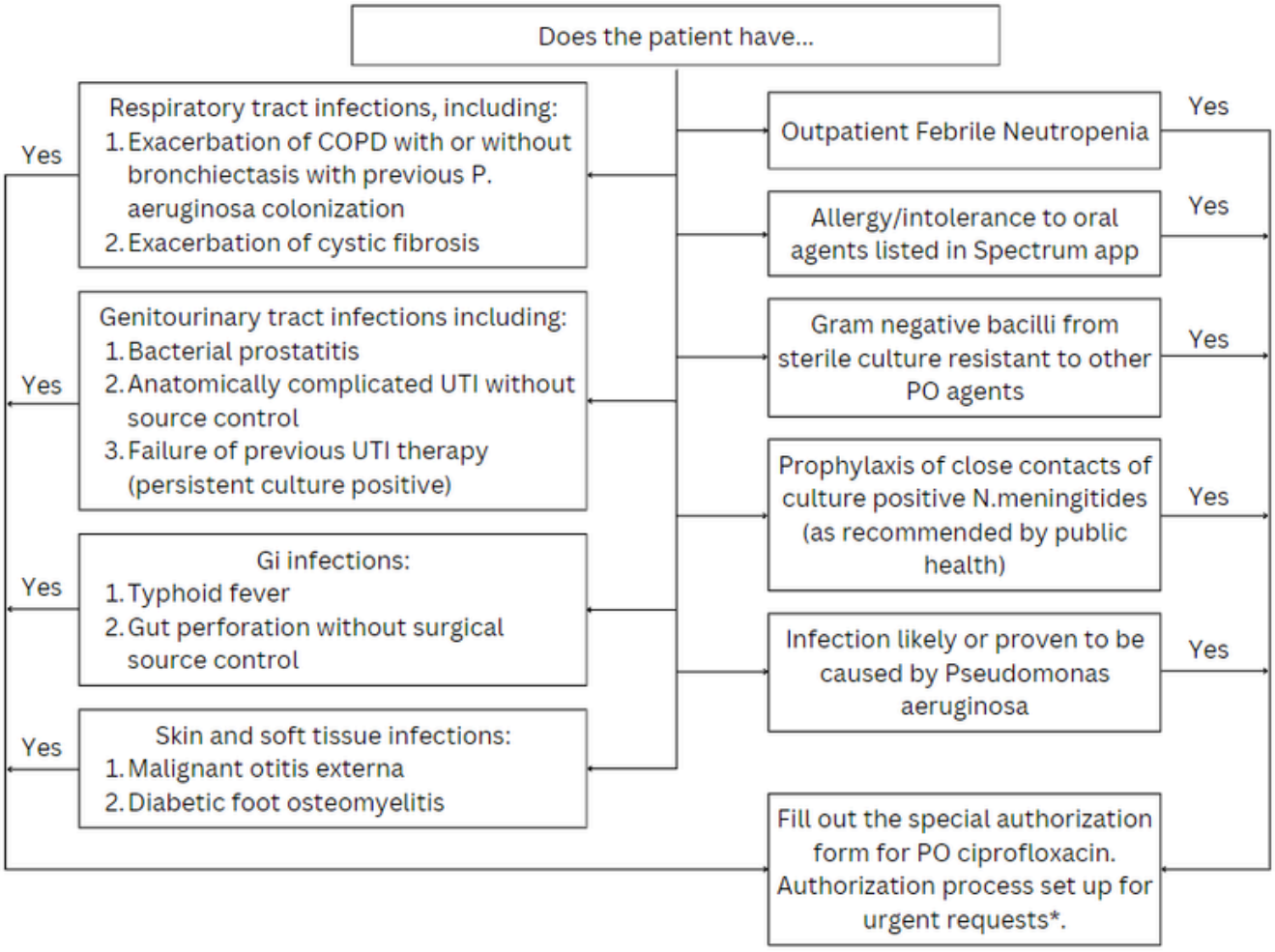
1. They do not recommend treatment of adolescents and adults with short-acting beta-agonists (SABA) alone. All patients should receive an ICS-containing controller treatment to reduce risk of serious exacerbations and to control symptoms.
2. For best treatment outcomes, an ICS-containing controller treatment should be initiated as soon as possible after a diagnosis of asthma is made. This is because the evidence suggests that:
    a. Early initiation of low dose ICS in patients with asthma leads to a greater improvement in lung function than if symptoms have been present for more than 2-4 years.
    b. Patients not taking an ICS who experienced a severe exacerbation have greater long-term decline in lung function versus those who have already started taking an ICS.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2025. Available from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/
2. Global Initiative for Asthma. Global Strategy for asthma management and prevention [internet]. Updated 2024. Available from: https://ginasthma.org/gina-reports
3. Kaplan, A. Asthma in Adults and Adolescents. In: CPS Full Access [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2022 [updated May 2021; cited 2022 March 15]. Available from: https://myrxtx.ca

ORAL FLUOROQUINOLONES

COVERAGE ALGORITHM: PO CIPROFLOXACIN TABLETS



*Urgent request turnaround is 1-2 business days. The vast majority of urgent requests are completed same day, but if many requests are received late in the day, some may carry over to the next day. Requests requiring additional information will take longer to process.

TIPS

- Use the Oral Ciprofloxacin Tablets Special Authorization Form.
- Coverage for ciprofloxacin liquid (Cipro oral suspension 10 g/100mL) will be granted if all special authorization criteria from the “Oral Fluoroquinolones” section are met.
- The First Line/Spectrum app (www.Spectrum.app) is free to all prescribers and contains provincial guidelines on appropriate antimicrobial use based on local resistance rates, provincial antibiogram trends and dose/duration recommendations.
- If a culture and sensitivity test is applicable, please include the results with the special authorization form. If the medication was recommended following an Infectious Disease Consultation, please document this as well.
- Special authorizations for PO ciprofloxacin are processed urgently; typically, coverage can be established the same day. Contacting the Pharmaceutical Services Division (709-729-6507) is the best way to inquire about processing times and identify urgent requests.

NLPDP CRITERIA FOR PO CIPROFLOXACIN TABLETS

For treatment of:

1. *Respiratory tract infections likely or proven to be caused by P. aeruginosa including:*
    a. Exacerbation of COPD with or without bronchiectasis, with previous P. aeruginosa colonization
    b. Exacerbation of cystic fibrosis
2. *Genitourinary tract infections likely or proven to be caused by P. aeruginosa including:*
    a. Bacterial prostatitis
    b. Anatomically complicated urinary tract infections without source control
    c. Failure of previous therapy for urinary tract infection (persistent culture positive)
3. *Skin and soft tissue infections likely or proven to be caused by P. aeruginosa:*
    a. Malignant otitis externa
    b. Diabetic foot osteomyelitis
4. *Gastrointestinal infections likely or proven to be caused by P. aeruginosa:*
    a. Typhoid fever
    b. Gut perforation without surgical source control
5. *Outpatient febrile neutropenia*
6. *Allergy or intolerance to oral agents listed in FirstLine app*
7. *Gram negative bacilli from sterile culture which is resistant to other oral agents*
8. *Prophylaxis of close contacts of culture positive N. meningitides, as recommended by public health.*
9. *As recommended by Infectious Disease specialist*

EVIDENCE FOR USE

Because of continuing concerns of emerging resistance, systemic fluoroquinolones should only be used to treat severe infections where the benefits outweigh the risks; specifically, in cases where there are no other alternatives available and the infection in question is likely or proven to be caused by susceptible bacteria. It is recommended to avoid fluoroquinolones for the treatment of acute sinusitis, mild exacerbations of chronic bronchitis, and uncomplicated UTI unless there are no other treatment options available. Development of resistance has been seen in multiple bacteria, including MRSA, P. aeruginosa, and anaerobes. Particularly concerning, however, has been the development of resistance seen in bacteria causing community-acquired infections. In a report from Choosing Wisely NL from 2020, rates of ciprofloxacin resistant E.coli were 18% in NL (considered high).

RENAL DOSING CONSIDERATIONS

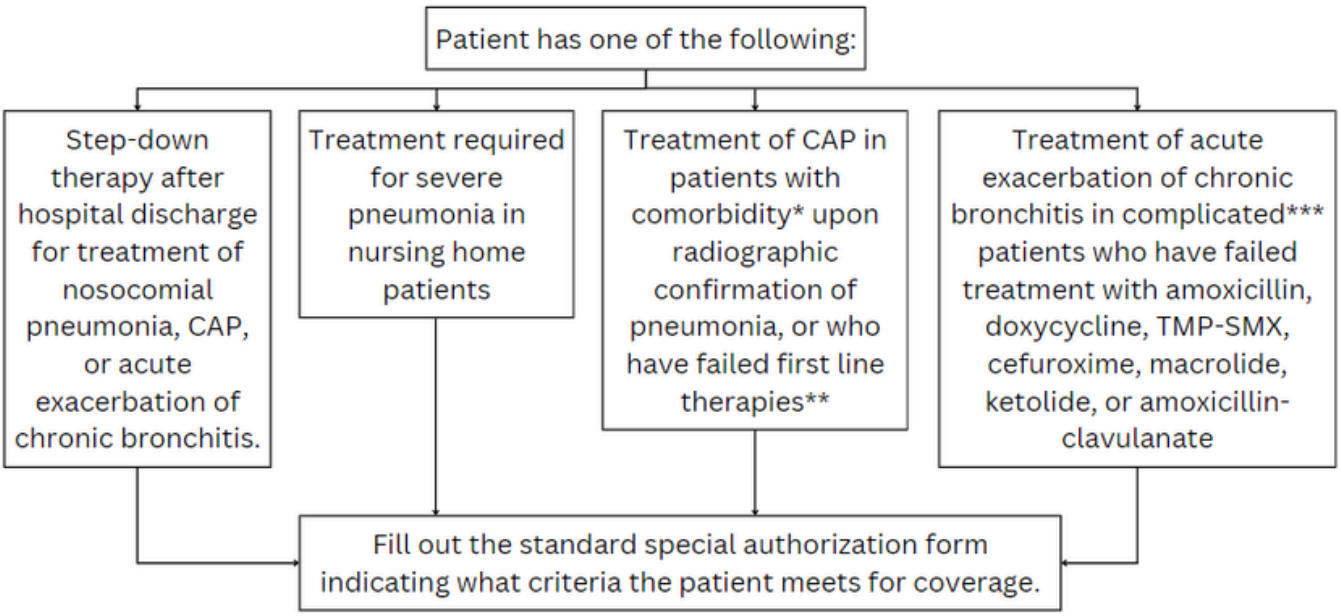
Ciprofloxacin - PO (immediate-release tablet or suspension)

- CrCl 31-60 mL/min: maximum daily dose 1000 mg
- CrCl ≤ 30 mL/min: maximum daily dose 500 mg
- Dialysis: Ciprofloxacin: For hemodialysis patients, follow dosing for CrCl <30 mL/min.
  On days of dialysis, give the dose after dialysis.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2022. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. CPhA Monograph. Fluoroquinolones. In: Compendium of Therapeutic Choices [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2022 [updated March 2018; cited 2022 March 23]. Available from: https://www.myrxtx.ca
3. Dalhoff A. Global fluoroquinolone resistance epidemiology and implications for clinical use. Interdiscip Perspect Infect Dis [Internet]. 2012;2012:976273. Available from: http://dx.doi.org/10.1155/2012/976273
4. Quality of Care NL. COMMUNITY QUALITY OF CARE Modest Reduction in Use of Oral Antibiotics by Health Care Providers but Continued High Inappropriate Use of Ciprofloxacin [Internet]. Qualityofcarenl.ca. [cited 2022 Mar 24]. Available from: https://qualityofcarenl.ca/wp-content/uploads/2020/09/Modest-Reduction-in-Use-of-Oral-Antibiotics-by-Health-Care.pdf
5. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2018 Mar 1; cited 2023 Apr 3]. Fluoroquinolones [CPhA Monograph]. Available from http://www.myrxtx.ca.

COVERAGE ALGORITHM: RESPIRATORY FLUOROQUINOLONES (LEVOFLOXACIN, MOXIFLOXACIN)



***** Comorbidities include chronic lung disease, malignancy, diabetes, liver, renal, or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition, or acute weight loss

****** First line therapies include macrolide, doxycycline, amoxicillin-clavulanate. Patients only need to fail one first line therapy to qualify for coverage.

***See definition of complicated patients below

TIPS

- Use the Standard Special Authorization Form.
- The Spectrum app (www.Spectrum.app) is free to all prescribers and contains provincial guidelines on appropriate antimicrobial use based on local resistance rates, provincial antibiogram trends and dose/duration recommendations.
- For treatment of CAP in patients:
  - Treatment of CAP in patients with comorbidity* upon radiographic confirmation of pneumonia, or who have failed first line therapies**:
    - *: comorbidities include chronic lung disease, malignancy, diabetes, liver, renal, or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition, or acute weight loss **OR**
    - **: first line therapies include macrolide, doxycycline, amoxicillin-clavulanate. Patients only need to fail one first line therapy to qualify for coverage.
- Complicated acute exacerbation of chronic bronchitis (AECB) is defined as increased cough and sputum, sputum purulence and increased dyspnea, **AND**
  - FEV <50% predicted **OR**
  - FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

EVIDENCE

Because of continuing concerns of emerging resistance, systemic fluoroquinolones should only be used to treat severe infections where the benefits outweigh the risks; specifically, in cases where there are no other alternatives available and the infection in question is likely or proven to be caused by susceptible bacteria. It is recommended to avoid fluoroquinolones for the treatment of acute sinusitis, mild exacerbations of chronic bronchitis, and uncomplicated UTI unless there are no other treatment options available. Development of resistance has been seen in multiple bacteria, including MRSA, P. aeruginosa, and anaerobes. Particularly concerning, however, has been the development of resistance seen in bacteria causing community-acquired infections. Although respiratory quinolones, such as moxifloxacin and levofloxacin, are effective for treatment of respiratory infections, their broad spectrum activity coupled with overuse results in high rates of resistance. As a result, quinolone use should not be first-line (unless treating prostatitis or P. aeruginosa infection).

RENAL DOSING CONSIDERATIONS

Levofloxacin

- CrCl 20-49 mL/min
  - If usual dose is 750 mg Q24H: change to 750 mg Q48H
  - If usual dose is 500 mg Q24H: change to 500 mg initially then 250 mg Q24H
  - If usual dose is 250 mg Q24H: no dosage adjustment required
- CrCl 10-19 mL/min
  - If usual dose is 750 mg Q24H: change to 750 mg initially then 500 mg Q48H
  - If usual dose is 500 mg Q24H: change to 500 mg initially then 250 mg Q48H
  - If usual dose is 250 mg Q24H: change to 250 mg Q48H
- CrCl <10 mL/min
  - If usual dose is 750 mg Q24H: change to 500 mg initially then 500 mg Q48H
  - If usual dose is 500 mg Q24H: change to 500 mg initially then 250 mg Q48H
  - If usual dose is 250 mg Q24H: change to 250 mg Q48H
- Dialysis
  - Follow dosing for CrCl 10-19 mL/min

Moxifloxacin

- No dosage adjustment is required

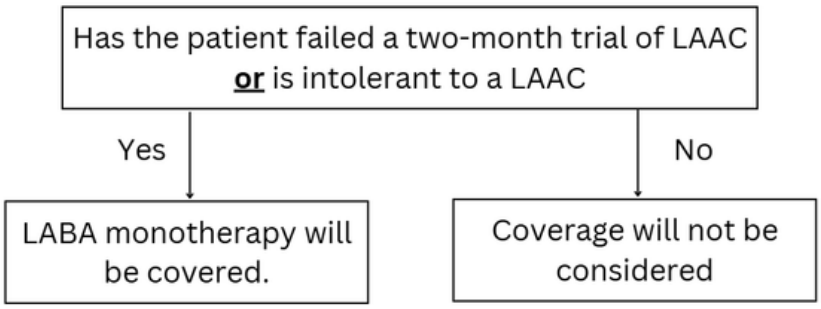
REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2022. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. CPhA Monograph. Fluoroquinolones. In: Compendium of Therapeutic Choices [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2022 [updated March 2018; cited 2022 March 23]. Available from: https://www.myrxtx.ca
3. Dalhoff A. Global fluoroquinolone resistance epidemiology and implications for clinical use. Interdiscip Perspect Infect Dis [Internet]. 2012;2012:976273. Available from: http://dx.doi.org/10.1155/2012/976273
4. Quality of Care NL. COMMUNITY QUALITY OF CARE Classes of Antibiotics Used in the Community and Overuse of Fluoroquinolones. [Internet]. Qualityofcarenl.ca. [cited 2022 April 8]. Available from: https://qualityofcarenl.ca/wp-content/uploads/2021/02/Classes-of-Antibiotics-Used-in-the-Community-and-Overuse-of-Quinolones.pdf
5. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2018 Mar 1; cited 2023 Apr 3]. Fluoroquinolones [CPhA Monograph]. Available from http://www.myrxtx.ca.

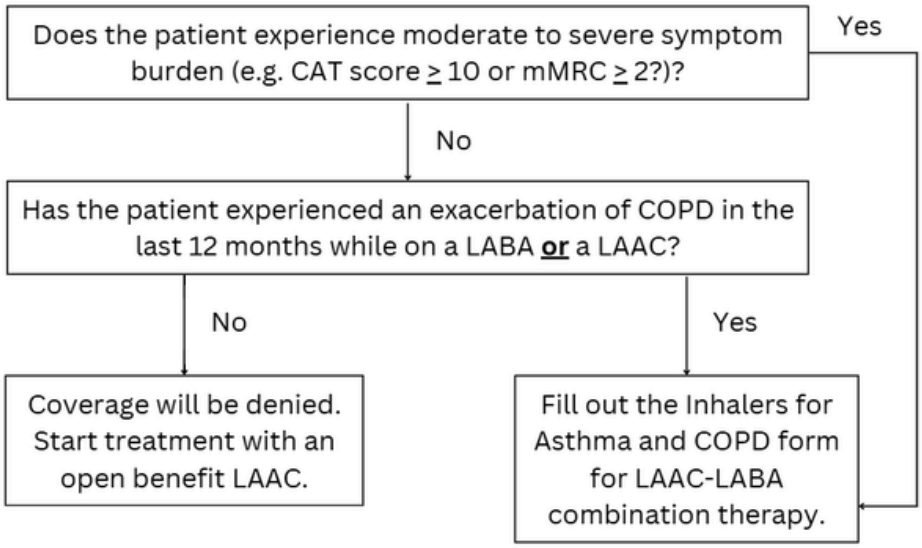
CHRONIC OBSTRUCTIVE PULMONARY DISEASE

LAAC MONOTHERAPY (e.g., tiotropium (Spiriva), umeclidinium (Incruse Ellipta), and aclidinium (Tudorza Genuair)) ARE OPEN BENEFIT UNDER NLPDP.

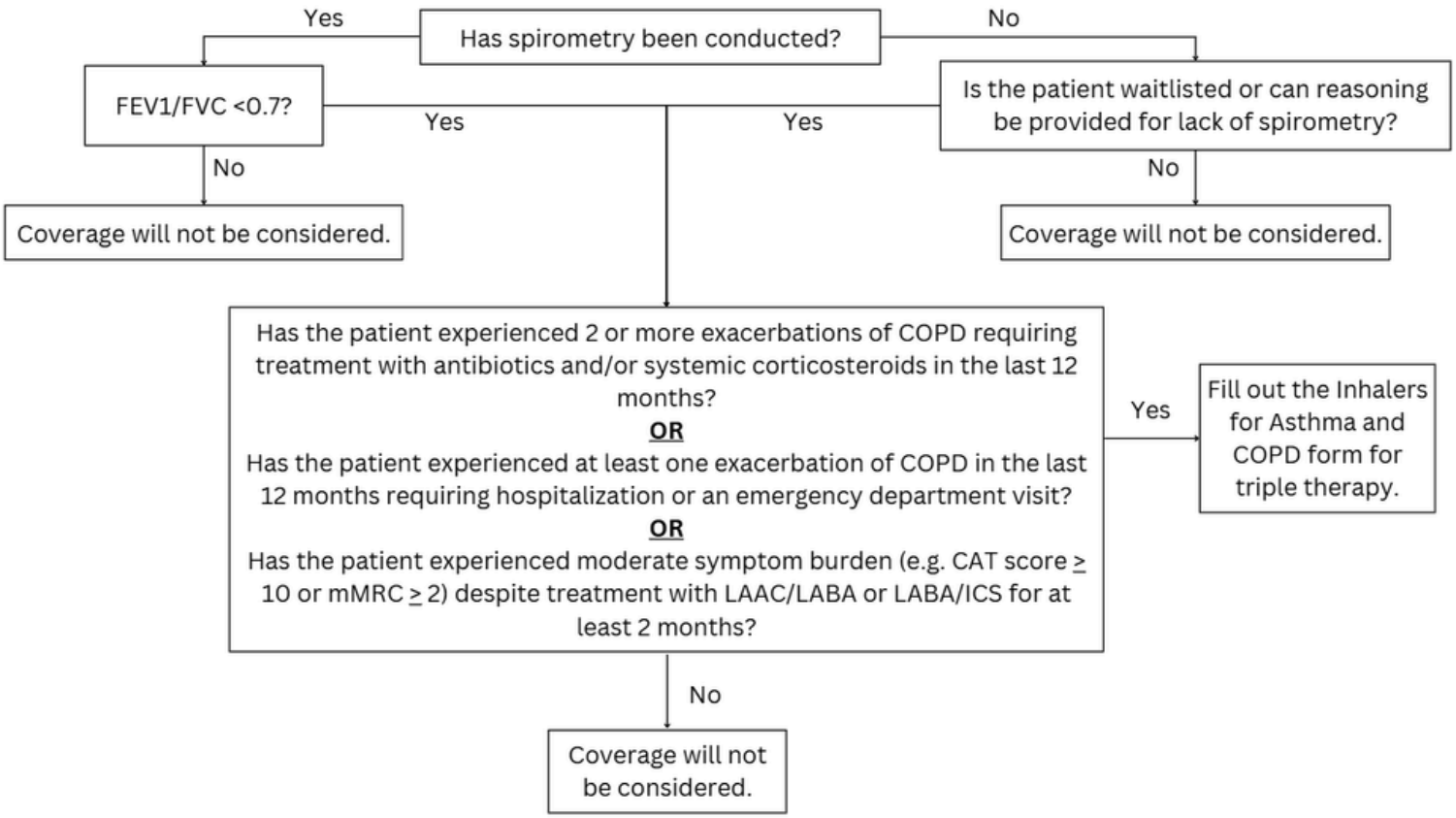
COVERAGE ALGORITHM: LABA (FORMOTEROL, SALMETEROL) MONOTHERAPY



COVERAGE ALGORITHM: LAAC-LABA COMBINATION THERAPY



COVERAGE ALGORITHM: TRIPLE THERAPY



TIPS

- Use the Inhalers for Asthma and COPD Form.
- COPD diagnosis is defined as FEV1/FVC < 0.7.
- Spirometry is only required for coverage of triple therapy. Spirometry from any point in time will be considered. If spirometry is not conducted, provide reasoning and other evidence regarding severity (e.g., mMRC score of at least Grade 2)
  - mMRC Grade 2 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
- NLPDP will only cover one maintenance inhaler at a time per patient. (i.e. will not consider coverage of LAAC+LABA through separate inhalers)
  - If a claim is made for a LAAC inhaler or LAAC/LABA inhaler in the previous 6 months, open benefit ICS inhalers claims will be rejected; special authorization is required for intensifying therapy.
  - If a claim is made for LABA/ICS or LAAC/LABA/ICS inhaler in the previous 6 months, open benefit ICS inhalers claims will be rejected for duplication of therapy.
- Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring triple therapy (Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg).
- LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as triple therapy for COPD in patients who cannot use Trelegy 100 or Breztri. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

AVAILABLE PRODUCTS AND COVERAGE

Class	Brand Name *(formulations)*	Generic	Coverage
SABA	Ventolin *(pMDI, Diskus, Nebules)*	Salbutamol	*MDI:* OB *Nebules:* SA
	Bricanyl *(DPI)*	Terbutaline	OB
SAMA	Atrovent *(pMDI, nebules)*	Ipratropium	*MDI:* OB *Nebules:* SA
SABA-SAMA combination	Combivent *(Respimat, UDV)*	Salbutamol-Ipratropium	*Respimat:* OB *UDV:* SA
LAAC	Tudorza (*Genuair DPI)*	Aclidinium	OB
	Spiriva *(DPI, Respimat SMI)*	Tiotropium	OB
	Incruse *(Ellipta DPI)*	Umeclidinium	OB
LABA	Foradil *(DPI)*	Formoterol fumarate	SA
	Oxeze *(Turbuhaler)*	Formoterol fumarate dihydrate	SA
	Serevent *(Diskhaler, Diskus)*	Salmeterol	SA
LAAC-LABA combination	Duaklir (Genuair DPI)	Aclidinium/formoterol fumarate dihydrate	SA
	Ultibro *(Breezhaler DPI)*	Glycopyrronium/indacaterol	SA
	Inspiolto *(Respimat SMI)*	Tiotropium/olodaterol	SA
	Anoro *(Ellipta DP)*	Umeclidinium/vilanterol	SA
ICS-LABA combination	Symbicort *(Turbuhaler DPI)*	Budesonide/formoterol fumarate dihydrate	SA
	Advair *(pMDI, Diskus DPI)*	Fluticasone/salmeterol	SA
	Breo *(Ellipta DPI)*	Fluticasone/vilanterol	SA
ICS-LABA-LAAC combination	Trelegy *(Ellipta DPI)*	Fluticasone/umeclidinium/vilanterol	SA
	Breztri (Aerosphere)	Budesonide/glycopyrronium/formoterol fumarate dihydrate	SA

DPI: dry powder inhaler; ICS: inhaled corticosteroid; LAAC: long-acting-anticholinergic agent; LABA: long-acting beta2-adrenergic agonist; OB: open benefit; pMDI: pressurized metered dose inhaler; SA: special authorization SABA: short-acting beta agonists; SAMA: short-acting muscarinic antagonist; SMI: soft mist inhaler; UDV: unit dose vials

EVIDENCE FOR USE

Therapy for COPD is managed in a stepwise manner, taking into account individual patient presentation and preference. Main goals of therapy include preventing disease progression, reducing the frequency and severity of exacerbations, reducing mortality, reducing symptoms, increase physical activity and exercise tolerance, and improving overall health status. Patients with COPD should be encouraged to maximize exercise and activity, address risk factors such as smoking, and create a self-management plan to recognize early and treat these exacerbations according to a prespecified action plan.

All patients should be provided with a short acting bronchodilator PRN (e.g. salbutamol), and be provided education on proper inhaler technique. For detailed information on guideline recommended prescribing practices for various COPD presentations, please see the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2024 Pocket Guide.

ASTHMA/COPD OVERLAP (ACO)

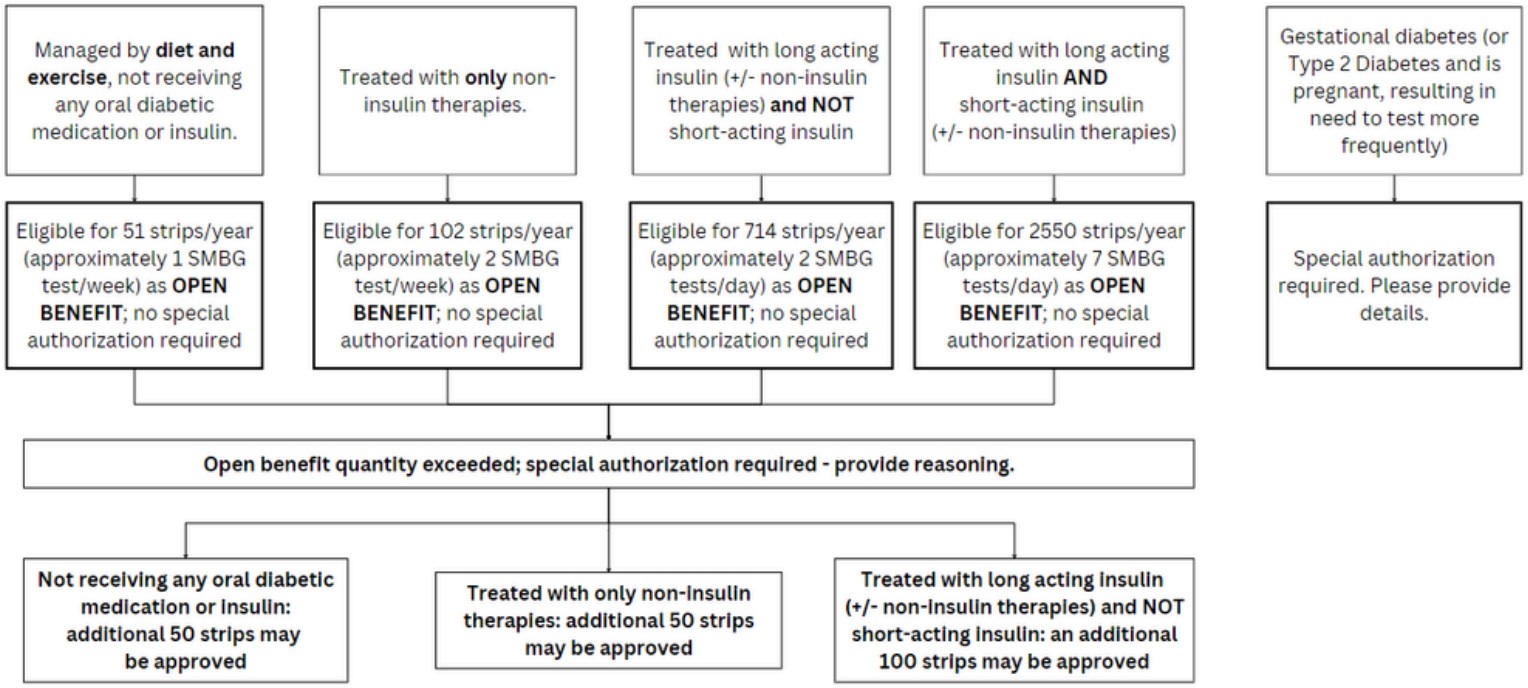
- Patients with ACO will be approved for LABA/ICS combination as first-line therapy based on patient history and lung function studies indicating an ACO diagnosis
  - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc.).
  - LABA/ICS combinations covered for ACO include: budesonide/formoterol dihydrate (Symbicort), fluticasone/salmeterol (Advair), fluticasone/vilanterol (Breo), and mometasone/formoterol (Zenhale)
- If response to LABA/ICS combination is not adequate after a 2 month trial, triple therapy may be approved.
  - Please follow the above flowchart for triple therapy to determine patient eligibility.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2022. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Bourbeau J, Bhutani M, Hernandez P, Aaron S, Balter M, Beauchesne M et al. Canadian Thoracic Society Clinical Practice Guideline on pharmacotherapy in patients with COPD – 2019 update of evidence. Canadian Journal of Respiratory, Critical Care, and Sleep Medicine. 2019;3(4):210-232.
3. McIvor, R. Chronic Obstructive Pulmonary Disorder. In: Compendium of Therapeutic Choices [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2022. [updated April 2021; cited 2022 April 10]. Available from: https://www.myrxtx.ca
4. Global Initiative for Chronic Obstructive Lung Disease, Inc. Pocket Guide to COPD Diagnosis, Management, and Prevention: A Guide for Health Care Professionals 2023 Edition. 2024. Available from: https://goldcopd.org/wp-content/uploads/2024/02/POCKET-GUIDE-GOLD-2024-ver-1.2-11Jan2024_WMV.pdf

DIABETIC TEST STRIPS

COVERAGE ALGORITHM: TEST STRIP APPROVAL



TIPS

- Use the test strip special authorization form.
- If Special Authorization is approved under Exceptional Circumstances:
  - Beneficiaries managed by DIET AND EXERCISE, not receiving any diabetic oral medication or insulin, will be authorized for additional 51 test strips annually; fill dates must be at least 6 months apart. Beneficiaries receiving diabetic ORAL MEDICATIONS only will be authorized for an additional 51 test strips annually.
  - Beneficiaries receiving LONG ACTING INSULIN (and not using short acting insulin) will be authorized for an additional 102 test strips annually.
- The annual maximum number of test strips can be accessed every 12 month period. and is based on the 12 months preceding the day you are filling a prescription. A 12 month period is equal to 365 full days. The rollover will occur on day 366.
- If you are unsure of the number of test strips you can access for the remainder of the year, you can call the NLPDP office at (709) 729-6507 or toll free at 1-888-222-0533 and press option #1

It is up to the provider submitting the special authorization to provide reasoning for requirement of additional test strips within the authorization form. Examples of reasoning for additional test strips includes:

1. Increased testing requirements due to concomitant medication use (e.g. initiation of medication that causes hyperglycemia such as oral steroids) or disease states not listed in the algorithm above.
2. Periods of illness in which PO intake is expected to be abnormal (particularly important for patients using basal-bolus insulin, those using insulin pumps, and individuals who are taking oral medications that directly affect insulin production) and/or the patient is at an increased risk of experiencing hypoglycemia due to an acute illness.
3. Patients trying to conceive.
4. Significant changes in routine or changes in drug dose/regimen.
5. Cases where hypoglycemia poses a safety hazard at work.

For providers requesting for additional test strips for extenuating circumstances, please include the following information in your request:

- Number of times per day the beneficiary has been instructed to test
- How long increased testing will be required (ex, 2 weeks, 1 month, three months, etc)
- How often the results are reviewed by a health professional
- Specific actions that will be taken based on the results (ex. change therapy, change medication dose, etc)
- Any other relevant information to support additional testing

Note: Typically in a setting where increased testing demands are required (for example, during acute illness), authorization may be delayed compared to the need for a change in testing requirements. Indicating on the form the urgency of the request, in addition to following up directly with the assessment office the same day of submission, can help expedite the approval process.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2024. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.

NEUROPATHIC PAIN

As of December 15, 2025, gabapentin, pregabalin, and duloxetine are open benefit with some limitations as stated below.

Gabapentin:
100 mg, 300 mg, 400 mg, 600 mg, 800 mg

Limitations: Gabapentin will not be reimbursed concurrently with Pregabalin.

Pregabalin
25 mg, 50 mg, 75 mg, 150 mg, 225 mg, 300 mg

Limitations: Pregabalin will not be reimbursed concurrently with Gabapentin. Combinations of two or more strengths will not be considered concurrently under any circumstances.

Quantity limits are as follows:

- 25 mg – 3/day
- 50 mg – 4/day
- 75 mg – 3/day
- 150 mg – 2/day
- 225 mg – 2/day
- 300 mg – 2/day

Duloxetine
30 mg and 60 mg

Limitations: Combination of the 30 mg and 60 mg strength concurrently will not be considered.

Quantity limits are as follows:

- 30 mg – 2/day
- 60 mg – 1/day

EVIDENCE FOR USE

First line treatment options for neuropathic pain include gabapentinoids, tricyclic antidepressants, and SNRIs (venlafaxine and duloxetine). Since neuropathic pain treatment varies significantly between individuals, trials of multiple medications from different classes may be required to find a suitable agent. Selection of initial therapy may also be guided by comorbid conditions and concurrent medications.

The gabapentinoids, despite being considered a first line option, are significantly more expensive compared to the other first line agents such as TCA's and venlafaxine (both open benefits). Similarly, although duloxetine has the largest amount of evidence for efficacy, it is listed under special authorization despite being approved for numerous neuropathic pain conditions.

RENAL DOSING CONSIDERATIONS

Pregabalin

- CrCl 30-60 mL/min: maximum daily dose 300 mg given in divided BID or TID doses
- CrCl 15-30 mL/min: maximum daily dose 150 mg given once daily or divided BID
- CrCl <15 mL/min: maximum daily dose 75 mg given once daily

Gabapentin

- CrCl 30-59 mL/min: maximum daily dose 400-1400 mg given in divided doses BID
- CrCl 15-29 mL/min: maximum daily dose 200-700 mg given once daily
- CrCl 15 mL/min: maximum daily dose 100-300 mg given once daily
- CrCl <15 mL/min: reduce daily dose in proportion to creatinine clearance (i.e. patients with a CrCl of 7.5 mL/min should receive one- half the daily dose that patients with a CrCl of 15 mL/min receive)
- Hemodialysis: 125-350 mg per day; patients should receive maintenance doses as indicated and an additional post-hemodialysis dose administered after each 4 hours of hemodialysis.

Duloxetine

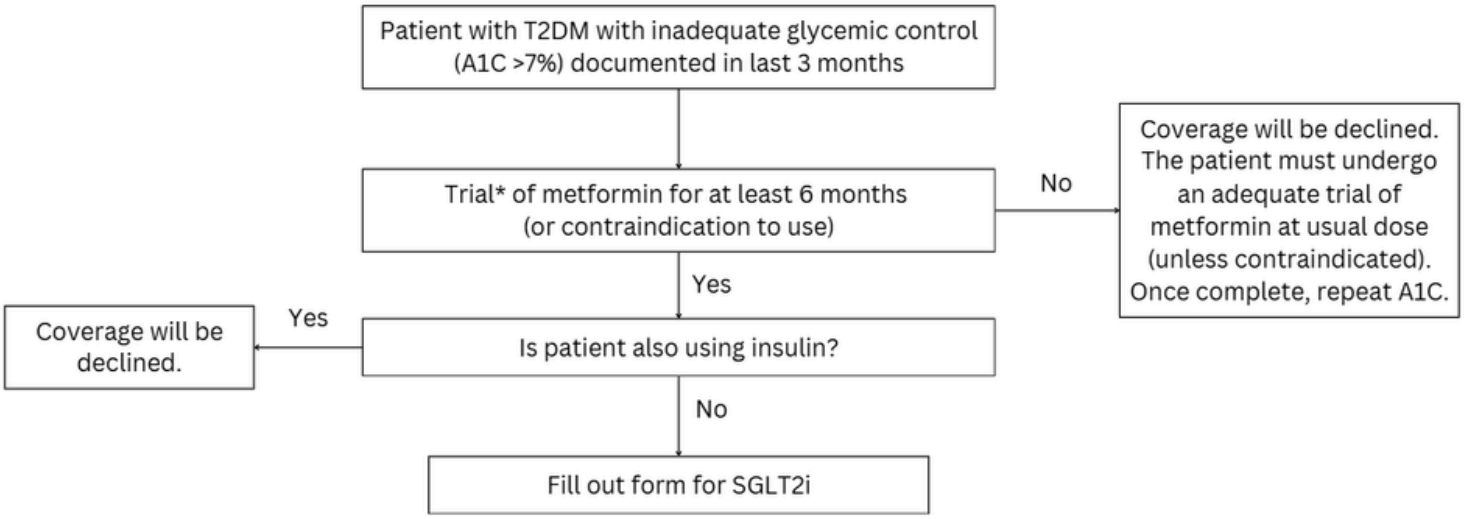
Not recommended for use in patients with end-stage renal disease (requiring dialysis) or in severe renal impairment (CrCl <30 mL/min).

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2026. Available from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/
2. Pharmacologic management of chronic neuropathic pain: Review of the Canadian Pain Society consensus statement. Alex Mu, Erica Weinberg, Dwight E. Moulin and Hance Clarke. Canadian Family Physician November 2017, 63 (11) 844-852
3. Tauben, D., Sracey, B. Pharmacologic management of chronic non-cancer pain in adults. In: UpToDate [Internet]. Waltham, MA: Wolters Kluwer; c2022. [updated March 2022; cited 2022 April 8]. Available from: https://www.uptodate.com/contents/pharmacologic-management-of-chronic-non-cancer-pain-in-adults
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2020 May 11; cited 2023 Apr 3]. Lyrica [Product Monograph]. Available from http://www.myrxtx.ca.
5. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2018 Aug 22; cited 2023 Apr 3]. Gabapentin Capsules [Product Monograph]. Available from http://www.myrxtx.ca.

NON-INSULIN ANTIHYPERGLYCEMICS

COVERAGE ALGORITHM: SODIUM GLUCOSE CO-TRANSPORTER 2 INHIBITORS (NO CARDIOVASCULAR DISEASE)



**Trials must be of optimal dose and duration. if dose is below target, request must specify reason for same.*

TIPS

- **Dapagliflozin (Forxiga) is an open-benefit medication.**
- Use the Non-Insulin Anti-Diabetic Agents form
- Sodium glucose co-transporter 2 inhibitors (SGLT2Is) or glucagon-like peptide 1 receptor agonists (GLP1-RAs) are the preferred antihyperglycemic (after metformin) in patients with CVD. If your patient has T2DM and documented CV disease (prior MI, CVA, PAD, unstable IHD), empagliflozin (Jardiance) may be covered (see empagliflozin for CVD flowchart and use the Diabetes Mellitus Type 2 High Cardiovascular Risk form).
- For patients who have a contraindications or intolerances to metformin, details must be provided on the nature of the contraindication or intolerance. If the dose has been tapered or a low-dose has been trialed and the patient has experienced an intolerance, all details surrounding these instances must be included.
    - Examples of contraindications to use of metformin: allergy, acute or chronic metabolic acidosis, history of lactic acidosis, acute or chronic alcohol intake that exceeds safe limit (i.e., diagnosis of alcohol use disorder), severe renal impairment (i.e. CrCl <30 mL/min).
- If coverage is obtained and the medication is well tolerated, NLPDP will cover the combination product with metformin, if desired, to enhance compliance (Synjardy for empagliflozin).
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after an SGLT2I is approved.
- **For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.**

EVIDENCE FOR USE

- Lowering of A1c ~0.7-0.9% (decreases with eGFR).
- Reduction in weight ~2 kg (decreases with eGFR).
- Reduction in MACE
  - Statistically significant for empagliflozin and canagliflozin in EMPA-REG and CANVAS trials, respectively.
  - Non-inferior for dapagliflozin in DECLARE-TIMI 58). These trials also showed beneficial evidence for use in HF and CKD.
- Slowed progression of CKD
  - Statistically significant secondary endpoints in CANVAS, DECLARE-TIMI 58, EMPA-REG Trials; confirmed as primary endpoints in CREDENCE and DAPA-CKD, EMPA-Kidney Trial.
- Reduction in worsening HF, CV death, and mortality
  - Statistically significant for dapagliflozin in DAPA-HF.
  - Reduced CV death or hospitalization from heart failure (statistically significant for empagliflozin in EMPEROR-Reduced).

RENAL DOSING CONSIDERATIONS

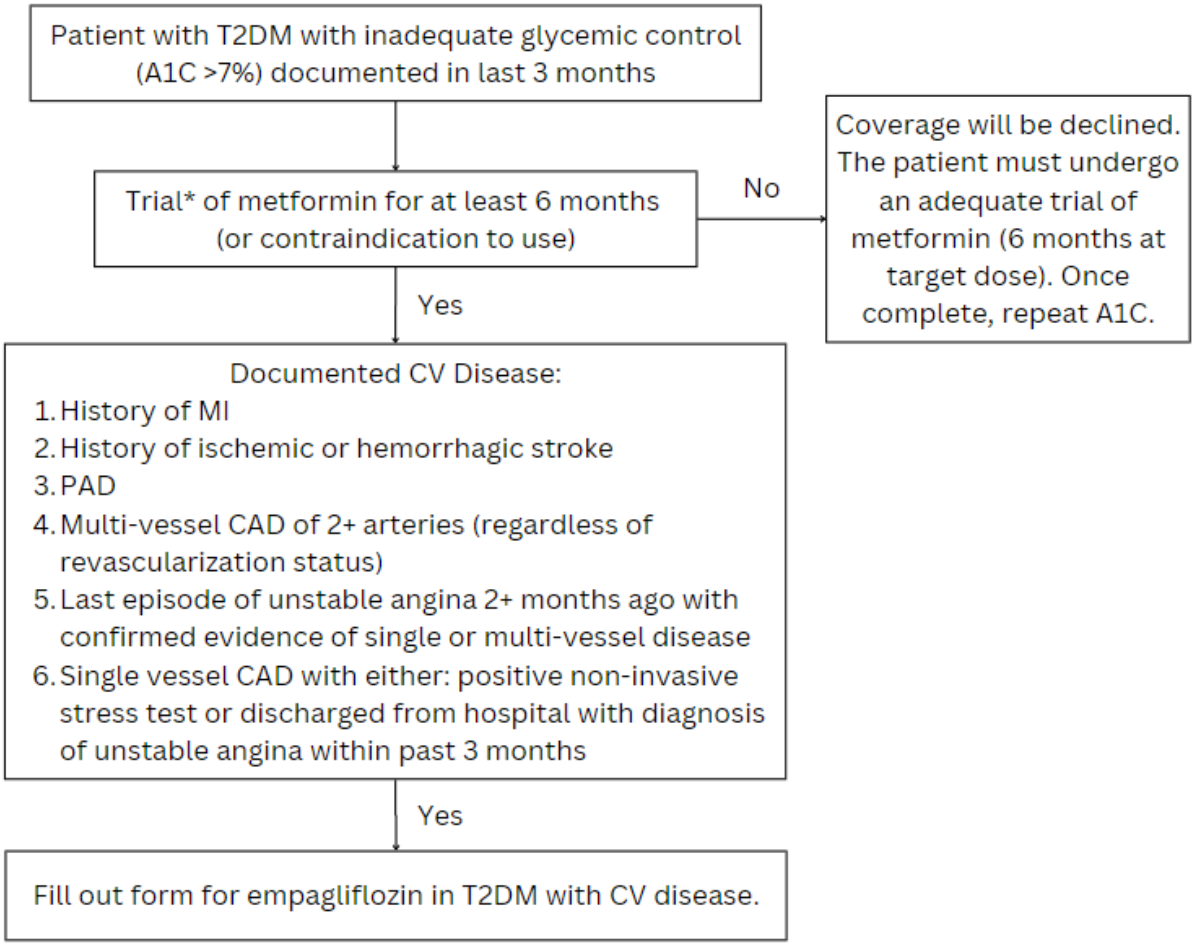
- Canagliflozin:
  - eGFR 15-30 ml/min: Limit dose to 100mg daily
  - Contraindicated if eGFR <15ml/min
- Dapagliflozin: Cardiorenal protection preserved, but less glycemic lowering effect with reduced renal function.
  - eGFR <45 mL/min: not recommended for glycemia lowering
  - eGFR <25 mL/min: initiation not recommended for glycemia lowering, however, patients using for CKD that are established on therapy may continue at 10 mg daily
- Emapgliflozin:
  - eGFR <30 mL/min: not recommended for glycemia lowering
    - In patients using for diabetic kidney disease previously established on treatment, a dose of 10 mg once daily can be continued (renal benefits have been shown in patients with eGFR $\geq$ 20 mL/min)

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2025. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Mansell K, Arnason T. Diabetes Mellitus. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 Jul 19; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
3. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Jul 19; cited 2022 Feb 9]. Metformin [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Sept 1; cited 2022 Feb 9]. Sulfonylureas [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
5. Wazney L, Kawchuk K, Hingwala J. Chronic Kidney Disease. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 May 12; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
6. Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. New England Journal of Medicine. 2015 Nov 26;373(22):2117-28.

7. Neal B, Perkovic V, Mahaffey KW, De Zeeuw D, Fulcher G, Erondu N, Shaw W, Law G, Desai M, Matthews DR. Canagliflozin and cardiovascular and renal events in type 2 diabetes. New England Journal of Medicine. 2017 Aug 17;377(7):644-57.
8. Wiviott SD, Raz I, Bonaca MP, Mosenzon O, Kato ET, Cahn A, Silverman MG, Zelniker TA, Kuder JF, Murphy SA, Bhatt DL. Dapagliflozin and cardiovascular outcomes in type 2 diabetes. New England Journal of Medicine. 2019 Jan 24;380(4):347-57.
9. Perkovic V, Jardine MJ, Neal B, Bompoint S, Heerspink HJ, Charytan DM, Edwards R, Agarwal R, Bakris G, Bull S, Cannon CP. Canagliflozin and renal outcomes in type 2 diabetes and nephropathy. New England Journal of Medicine. 2019 Jun 13;380(24):2295-306.
10. Heerspink HJ, Stefánsson BV, Correa-Rotter R, Chertow GM, Greene T, Hou FF, Mann JF, McMurray JJ, Lindberg M, Rossing P, Sjöström CD. Dapagliflozin in patients with chronic kidney disease. New England Journal of Medicine. 2020 Oct 8;383(15):1436-46.
11. McMurray JJ, Solomon SD, Inzucchi SE, Køber L, Kosiborod MN, Martinez FA, Ponikowski P, Sabatine MS, Anand IS, Bělohlávek J, Böhm M. Dapagliflozin in patients with heart failure and reduced ejection fraction. New England Journal of Medicine. 2019 Nov 21;381(21):1995-2008.
12. Packer M, Anker SD, Butler J, Filippatos G, Pocock SJ, Carson P, Januzzi J, Verma S, Tsutsui H, Brueckmann M, Jamal W. Cardiovascular and renal outcomes with empagliflozin in heart failure. New England Journal of Medicine. 2020 Oct 8;383(15):1413-24.

COVERAGE ALGORITHM: SODIUM GLUCOSE CO-TRANSPORTER 2 INHIBITORS WITH CV DISEASE



**If the trial was previous to 6-months ago NLPDP will still take it into consideration, pending reasoning explained (i.e., past trial of metformin with intolerance and discontinuation, at xx dose for xxx dates).*

TIPS

- Use the Diabetes Mellitus Type 2 High Cardiovascular Risk form
- NLPDP will only cover empagliflozin (Jardiance) for T2DM with established CV disease.
- SGLT2Is or GLP1-RAs are the preferred antihyperglycemic (after metformin) in patients with CVD.
- Please state date(s) of events and please provide the latest HgbA1c%. If the A1c is near target but the metformin dose is not optimized, we would need the reason, or would need to be advised that the metformin is at the max tolerated dose.
- Examples of contraindications to use of metformin: allergy, acute or chronic metabolic acidosis, history of lactic acidosis, acute or chronic alcohol intake that exceeds safe limit (i.e., diagnosis of alcohol use disorder), severe renal impairment (i.e. CrCl <30 mL/min).

NLPDP COVERAGE

- If coverage is obtained and the medication is well tolerated, NLPDP will cover the combination product with metformin, if desired, to enhance compliance (Synjardy).
- Approvals for Type 2 Diabetes Mellitus and Cardiovascular Disease are considered long term and do not require renewal requests (for this indication only)

EVIDENCE FOR USE

- Lowering of A1c ~0.7-0.9% (decreases with eGFR).
- Reduction in weight ~2 kg (decreases with eGFR).
- Reduction in MACE (statistically significant for empagliflozin in EMPA-REG trial). These trials also showed beneficial evidence for use in HF and CKD.
- Slowed progression of CKD (statistically significant secondary endpoints in EMPA-REG trial). Testing as a primary endpoint is currently underway in the EMPA-Kidney trial.
- Reduced CV death or hospitalization from heart failure (statistically significant for empagliflozin in EMPEROR-Reduced).

RENAL DOSING CONSIDERATIONS FOR EMPAGLIFLOZIN

- Less glycemic lowering effect with reduced renal function. Can be used for glycemia lowering if eGFR >45 mL/min.
- If eGFR is persistently less than 30 mL/min, empagliflozin should be discontinued.
- Contraindicated if eGFR <15mL/min

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2025. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Mansell K, Arnason T. Diabetes Mellitus. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 Jul 19; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
3. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Jul 19; cited 2022 Feb 9]. Metformin [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Sept 1; cited 2022 Feb 9]. Sulfonylureas [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
5. Wazney L, Kawchuk K, Hingwala J. Chronic Kidney Disease. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 May 12; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
6. Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. New England Journal of Medicine. 2015 Nov 26;373(22):2117-28.
7. Packer M, Anker SD, Butler J, Filippatos G, Pocock SJ, Carson P, Januzzi J, Verma S, Tsutsui H, Brueckmann M, Jamal W. Cardiovascular and renal outcomes with empagliflozin in heart failure. New England Journal of Medicine. 2020 Oct 8;383(15):1413-24.

COVERAGE ALGORITHM: SODIUM GLUCOSE CO-TRANSPORTER 2 INHIBITORS IN HEART FAILURE

TIPS

- As of July 2023, dapagliflozin (Forxiga) is an open benefit for any patient with NLPDP coverage. No special authorization form is required to be filled out.
- If an alternative SGLT2 inhibitor is required, a special authorization form must be filled out.
  - Of note: prior to July 2023, NLPDP would only cover dapagliflozin (Forxiga) for patients with NYHA class II - III heart failure with reduced ejection fraction (<40%) currently taking adjunct standard of care therapy. Other SGLT2 inhibitors were not considered.

EVIDENCE FOR USE

- Reduction in MACE
  - Non-inferior for dapagliflozin in DECLARE-TIMI 58. These trials also showed beneficial evidence for use in HF and CKD.
- Slowed progression of CKD
  - Statistically significant secondary endpoints in DECLARE-TIMI 58; confirmed as primary endpoints in DAPA-CKD.
- Reduction in worsening HF, CV death, and mortality
  - Statistically significant for dapagliflozin in DAPA-HF.

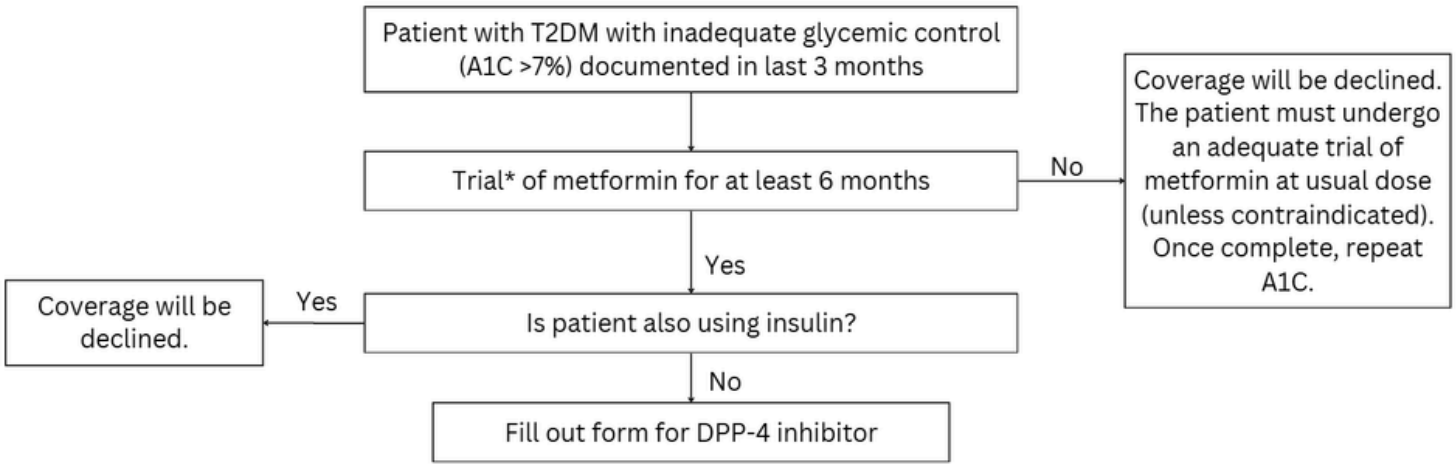
RENAL DOSING CONSIDERATIONS

- Dapagliflozin:
  - eGFR $\geq$ 25 mL/min: no dosage adjustment necessary for use in management heart failure.
  - eGFR < 25 mL/min: the manufacturer does not recommend initiating therapy, however, for patients previously established on dapagliflozin, 10 mg once daily can be continued.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2023. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Dapagliflozin. In: Specific Lexi-Drugs Online [database on the Internet]. Hudson (OH): Lexicomp Inc.: 2023 [updated 5 May. 2023; cited 24 May. 2023]. Available from: http://online.lexi.com. Subscription required to view.

COVERAGE ALGORITHM: DIPEPTIDYL PEPTIDASE-4 INHIBITOR



**If the trial was previous to 6-months ago NLPDP will still take it into consideration, pending reasoning explained (i.e., past trial of metformin with intolerance and discontinuation, at xx dose for xxx dates).*

TIPS

- NLPDP will only cover linagliptin (Trajenta), saxagliptin (Onglyza), and sitagliptin (Januvia). Fill out the "Non-Insulin Anti-Diabetic Agents" form.
- For patients who have a contraindications or intolerances to metformin, details must be provided on the nature of the contraindication or intolerance. If the dose has been tapered or a low-dose has been trialed and the patient has experienced an intolerance, all details surrounding these instances must be included.
  - Examples of contraindications to use of metformin: allergy, acute or chronic metabolic acidosis, history of lactic acidosis, acute or chronic alcohol intake that exceeds safe limit (i.e., diagnosis of alcohol use disorder), severe renal impairment (i.e. CrCl <30 mL/min).
- If coverage is obtained and the medication is well tolerated, special authorization can be submitted for the coverage of the combination product with metformin, if desired, to enhance compliance (all three agents available as combination products with metformin: Jentadueto (linagliptin + metformin), Komboglyze (saxagliptin + metformin), and Janumet/Janumet XR (sitagliptin + metformin or metformin ER).
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after the oral medication is approved.
- **For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.**

EVIDENCE FOR USE

- Lowering of A1c ~0.5-0.8%

RENAL DOSING CONSIDERATIONS

Sitagliptin:

- eGFR 30-44ml/min: 50mg daily
- eGFR <30ml/min: 25mg daily

Saxagliptin:

- eGFR <45ml/min: 2.5mg daily
- eGFR <15ml/min: Use alternative agent

Linagliptin:

- No dosage adjustment required
- Only DPP4 inhibitor that does not accumulate at lower eGFR

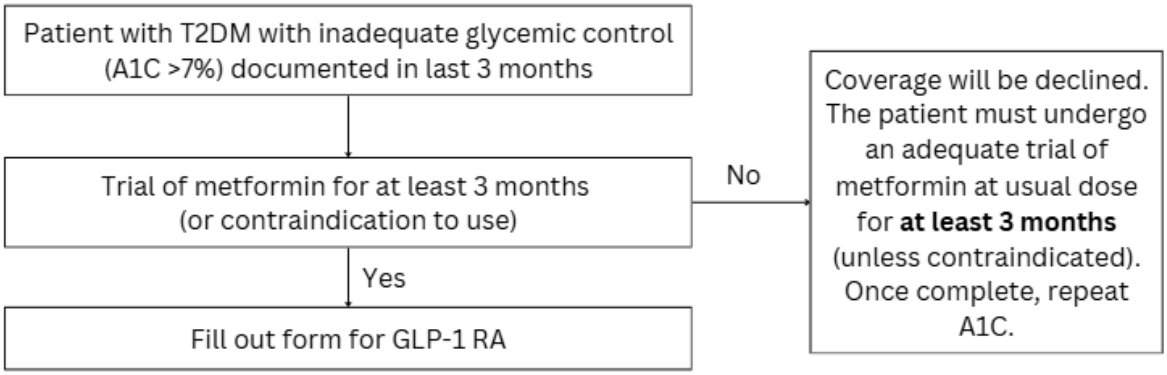
REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2025. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Mansell K, Arnason T. Diabetes Mellitus. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 Jul 19; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
3. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Jul 19; cited 2022 Feb 9]. Metformin [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Sept 1; cited 2022 Feb 9]. Sulfonylureas [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.

COMBINATION AGENTS:

Medication	Availability	Dosing Information
Invokamet (canagliflozin metformin)	50mg/500mg 50mg/1000mg 150mg/500mg 150mg/1000mg	Dose should be individualized based on efficacy and tolerability, and should be taken orally twice a day with meals to reduce the risk of GI AE associated with metformin. Dose escalation should be gradual to reduce GI AE associated with metformin. Maximum recommended daily dose: 150 mg canagliflozin/1000 mg metformin twice daily. Please see the product monograph for more information.
Synjardy (empagliflozin metformin)	5 mg/500mg, 5 mg/850mg, 5 mg/1000mg, 12.5 mg/500mg, 12.5 mg/850mg, 12.5 mg/1000mg	Recommended dose: one tablet twice daily with meals. The dosage should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability. Maximum recommended daily dose: 25 mg of empagliflozin and 2000 mg of metformin. Please see the product monograph for more information/
Janumuet (sitagliptin metformin)	50mg/500mg, 50mg/850mg, 50mg/1000mg **XR:** 50mg/500mg, 50mg/1000mg	Dose should be individualized based on current regimen, efficacy, and tolerability. Dose escalation should be gradual to reduce the GI AE associated with metformin. Maximum recommended daily dose: 100 mg sitagliptin and 2000 mg metformin. Please see the product monograph for more information.
Jentadueto (linagliptin metformin)	2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg	Dose should be individualized based on efficacy and tolerability, and should be taken orally twice a day with meals to reduce the risk of GI AE associated with metformin. Dose escalation should be gradual to reduce the incidence of GI AE with metformin. Maximum recommended daily dose: 5 mg linagliptin and 2000 mg metformin. Please see the product monograph for more information.
Komboglyze (saxagliptin metformin)	2.5mg/500mg 2.5mg/850mg 2.5mg/1000mg	Dose should be individualized based on efficacy and tolerability, and should be taken orally twice a day with meals to reduce the risk of GI AE associated with metformin. Dose escalation should be gradual to reduce the incidence of GI AE with metformin. Maximum recommended daily dose: 5 mg saxagliptin and 2000 mg metformin Please see the product monograph for more information.

COVERAGE ALGORITHM: GLUCAGON-LIKE PEPTIDE 1 RECEPTOR AGONISTS (SUBCUT AND PO)



The above algorithm applies to oral and subcutaneous formulations of semaglutide (Rybelsus and Ozempic)

TIPS

- Fill out the "Non-Insulin Anti-Diabetic Agents" form.
- Coverage for insulin glargine/lixisenatide (Soliqua) is addressed below.
- For patients who have a contraindication or intolerance to metformin, details must be provided on the nature of the contraindication or intolerance.
  - Examples of contraindications to use of metformin: allergy, acute or chronic metabolic acidosis, history of lactic acidosis, acute or chronic alcohol intake that exceeds safe limit (i.e., diagnosis of alcohol use disorder), severe renal impairment (i.e. CrCl <30 mL/min).
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.
- For semaglutide (Ozempic), the maximum dose for coverage is 1 mg once weekly.
- Oral semaglutide will not be considered in combination with injectable semaglutide.

EVIDENCE FOR USE

- Reduction in A1C ~1-1.5%
- Subcutaneous GLP-1 receptor agonists:
  - Reduction in MACE (statistically significant non-inferiority was demonstrated for semaglutide in SUSTAIN-6 trial). Other GLP1RAs have been evaluated for reduction in MACE in T2DM patients and have demonstrated statistically significant superiority (such as liraglutide in the LEADER trial).
  - Reduction in weight (although not indicated for weight loss, semaglutide has been evaluated for weight loss and has shown statistically significant reductions in weight vs. placebo in the STEP 1 trial).

RENAL DOSING CONSIDERATIONS

Semaglutide:

- No dose adjustment is required for patients with renal impairment.
- There is limited clinical experience in patients with severe renal impairment (eGFR <30 mL/min/1.73 m2), and caution should be used in this patient population.
- It is not recommended for use in patients with end-stage renal disease.

SOLIQUA (INSULIN GLARGINE/LIXISENATIDE)

INIDICATION FOR USE AND NLPDP COVERAGE CRITERIA:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) in combination with metformin.
  - Basal insulin includes insulin glargine (Basaglar, Lantus, Toujeo), degludec (Tresiba) and detemir (Levemir)
- Fill out the "Standard Special Authorization Form"

DOSING AND ADJUSTMENT

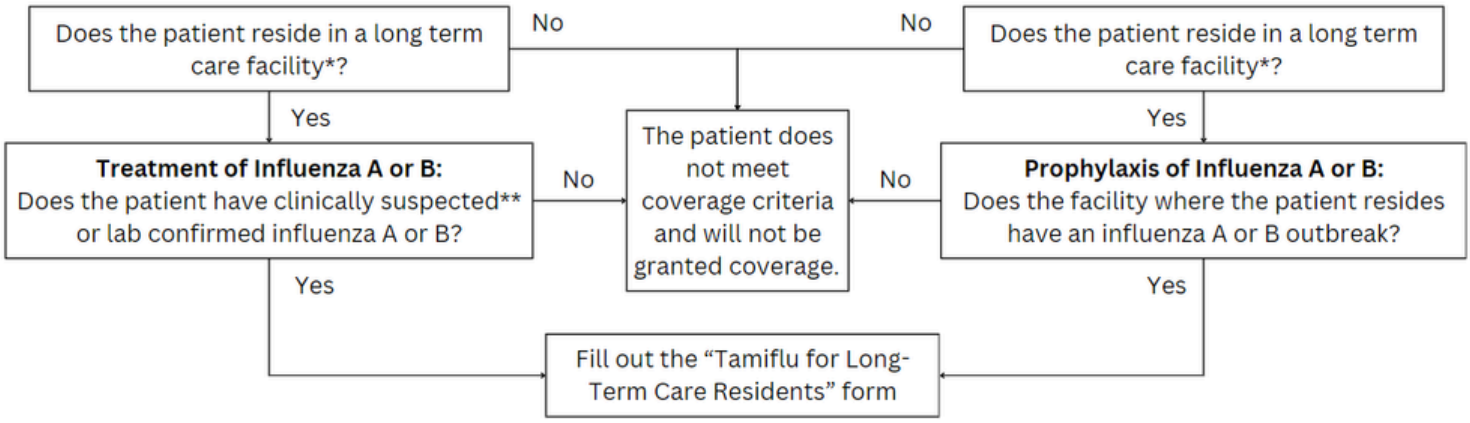
- Prior to initiation, basal insulin and/or other GLP-1RAs should be discontinued.
- Starting dose is based on prior basal insulin dose (not to exceed maximum recommended starting dose of lixisenatide of 10 mcg)
- After initiation, the dose can be titrated by 2-4 units weekly until fasting blood glucose targets are met
- Renal dosing considerations:
  - CrCl > 30 mL/minute: No dosage adjustment necessary
  - For CrCl <30 mL/min or in patients with renal impairment: there is very limited experience with lixisenatide in patients with severe renal impairment, and there is no information available for patients with end stage renal disease or those undergoing dialysis. Use in these patients is not recommended. As insulin requirements may be reduced as a result of reduced insulin metabolism, frequent glucose monitoring and dose adjustment as necessary is recommended. Close monitoring for lixisenatide related adverse reactions and for changes in renal function is recommended in these patients if therapy is initiated.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2025. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Mansell K, Arnason T. Diabetes Mellitus. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 Jul 19; cited 2022 Feb 9]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.
3. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Jul 19; cited 2022 Feb 9]. Metformin [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
4. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2019 Sept 1; cited 2022 Feb 9]. Sulfonylureas [CPhA Monograph]. Available from http://www.myrxtx.ca. Also available in paper copy from the publisher.
5. Marso SP, Bain SC, Consoli A, Eliaschewitz FG, Jódar E, Leiter LA, Lingvay I, Rosenstock J, Seufert J, Warren ML, Woo V. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. N Engl J Med. 2016 Nov 10; 375:1834-44.
6. Wilding JP, Batterham RL, Calanna S, Davies M, Van Gaal LF, Lingvay I, McGowan BM, Rosenstock J, Tran MT, Wadden TA, Wharton S. Once-weekly semaglutide in adults with overweight or obesity. New England Journal of Medicine. 2021 Feb 10; 384:989-1002.
7. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2022 Jan 4; cited 2023 Apr 3]. Ozempic [Product Monograph]. Available from http://www.myrxtx.ca.
8. CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2023 [updated 2021 Apr 30; cited 2023 May 19]. Soliqua [Product Monograph]. Available from http://www.myrxtx.ca.

OSELTAMIVIR

COVERAGE ALGORITHM: TAMIFLU FOR LONG TERM CARE RESIDENTS



**Long-term care facility refers to a licensed nursing home or personal care home.*

*** A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community*

TIPS

- Use the Tamiflu for Long Term Care Residents Special Authorization Form
- Oseltamivir is available as: 30 mg capsules, 45 mg capsules, and 75 mg capsules

NLPDP CRITERIA FOR OSELTAMIVIR COVERAGE

- Beneficiaries must be residents of a long term care facility (ie. licensed nursing home or personal care home) experiencing an influenza outbreak and treatment has been recommended by a Medical Officer of Health.
- **TREATMENT CRITERIA:** Patients outlined above must have lab confirmed influenza A or B OR have a clinically suspected case of influenza A or B (ie. patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community).
- **PROPHYLAXIS CRITERIA:** Eligible patients outlined above. Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility. 14 days prophylaxis coverage will be provided to eligible beneficiaries. Extended coverage can be provided on request if further confirmed cases are identified.

RENAL DOSING CONSIDERATIONS

Treatment dose (indicate dose based on patient creatinine clearance on form):

- 75mg twice daily for 5 days (CrCl >60ml/min)
- 75mg once daily for 5 days (CrCl 30-60ml/min)
- 30mg twice daily for 5 days (CrCl 30-60ml/min)
- 30mg once daily for 5 days (CrCl 10-30ml/min)

Prophylaxis dose (indicate based on patient creatinine clearance on form):

- 75mg once daily (CrCl >60ml/min)
- 75mg every second day (CrCl 30-60ml/min)
- 30mg once daily (CrCl 30-60ml/min)
- 30mg every second day (CrCl 10-30ml/min)

EVIDENCE FOR USE

Vaccination remains the preferred method to prevent influenza. Tamilfu is the first-line agent during outbreaks of influenza A and B and when taken as recommended, alleviates symptoms and reduces their duration (said to be controversial).

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2024. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Boyles S, Strang R. Influenza. In: CPS Full Access [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2024 [updated October 2023; cited 2024 April 3]. Available from: https://www-myrxtx-ca.qe2a-proxy.mun.ca/search

OSTEOPOROSIS

BISPHOSPHONATES

As of July 24 2025, PO alendronate and risedronate are open benefit with no limitations.

EVIDENCE FOR USE

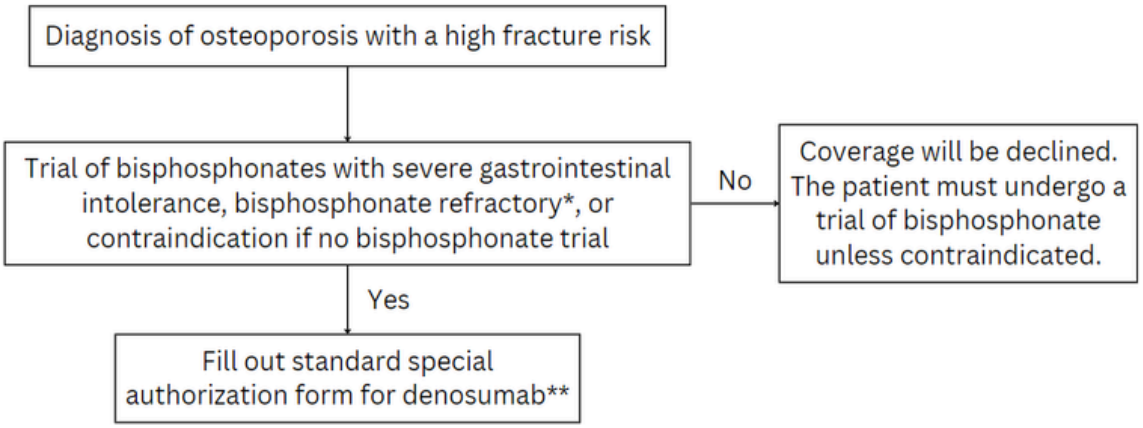
Bisphosphonates are the preferred osteoporosis treatment. The large clinical trials of alendronate, risedronate and zoledronate show a consistent reduction in relative risk of osteoporotic fracture in the range of 40–60%. Bisphosphonates are usually well tolerated.

Alendronate increases bone mass and reduces the risk of all fractures, including hip. Risedronate is also associated with a reduced risk of all osteoporosis-associated fractures.

RENAL DOSING CONSIDERATIONS

Alendronate: if CrCl <35 mL/minute, use not recommended
Risedronate: if CrCl <30 mL/minute, use not recommended

COVERAGE ALGORITHM: DENOSUMAB (JUBBONTI/STOBOCLO 60 MG/ML SYRINGE)



*Refractory is defined as a fragility fracture or evidence of decline in bone mineral density below pretreatment baseline levels, despite adherence for one year to osteoporosis therapy.
**Please provide the BMD report or results with T scores

TIPS

- Fill out the "Standard Special Authorization Form"
- As per NLPDP Biosimilar initiative, all new special authorization requests for Denosumab-naive patients will be for funded biosimilar Jubbonti or Stoboclo. Coverage for all patients previously on brand-name Prolia will continue until the transition date (September 1st 2025), at which time transition to Jubbonti is required.

NLPDP CRITERIA

High fracture risk is defined as:

- Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
- High 10-year fracture risk (≥ 20%) as defined b y the CAROC or FRAX tool
- CAROC tool can be found here: https://osteoporosis.ca/wp-content/uploads/CAROC.pdf
- FRAX tool can be found here: https://frax.shef.ac.uk/FRAX/

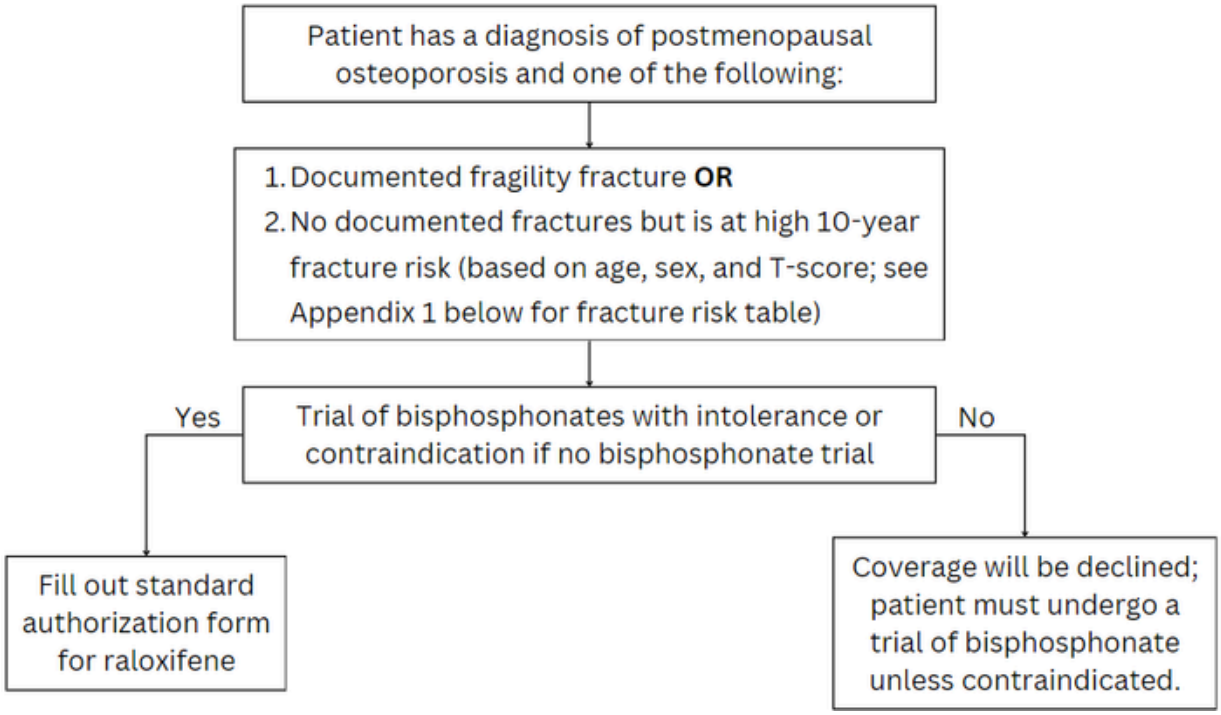
EVIDENCE FOR USE

Denosumab is considered first line therapy for postmenopausal women and males aged 50 years and older requiring osteoporosis treatment (alendronate, risedronate, and zoledronic acid are also first line). However, as denosumab is more expensive than generic bisphosphonate therapy, it is often used in those who have contraindications, substantial intolerances or barriers to bisphosphonates. Denosumab is not retained in the skeleton, and when therapy is stopped for more than 6 months, BMD gains are lost over 1–2 years; in saying this, the injection should not be delayed by more than 1 month due to the risk of rapid bone loss and vertebral fractures. Some studies suggest an increased risk of vertebral fracture in the first year after denosumab is discontinued.

RENAL DOSING CONSIDERATIONS

CrCl < 30 mL/min: Not contraindicated but at greater risk of developing hypocalcemia

COVERAGE ALGORITHM: RALOXIFENE (EVISTA & GENERICS)



TIPS

- Fill out the "Standard Special Authorization Form"

EVIDENCE FOR USE

Raloxifene prevents postmenopausal bone loss. It increases BMD by approximately 3% and reduces new vertebral fractures by 30–40%. It is a first-line option for menopausal women requiring osteoporosis treatment for the prevention of vertebral fractures. Of note, it is not recommended to be used in those who are at high risk of VTE.

RENAL DOSING CONSIDERATIONS

- Used with caution in patients with moderate or severe renal impairment.
- Negligible amounts of raloxifene are eliminated in urine. Trials show raloxifene and metabolite concentrations were not affected by renal function in women having CrCl as low as 21 mL/min.

APPENDIX 1: 10 YEAR ABSOLUTE FRACTURE RISK BASED ON BMD:

	WOMEN		
Age (yrs)	Low Risk (<10%)	Moderate Risk (10-20%)	High Risk (>20%)
50	> - 2.3	- 2.3 to - 3.9	< - 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to - 2.6	< - 2.6
70	> - 0.8	- 0.8 to - 2.2	< - 2.2
75	> - 0.7	- 0.7 to - 2.1	< - 2.1
80	> - 0.6	- 0.6 to - 2.0	< - 2.0
85	> - 0.7	- 0.7 to - 2.2	< - 2.2

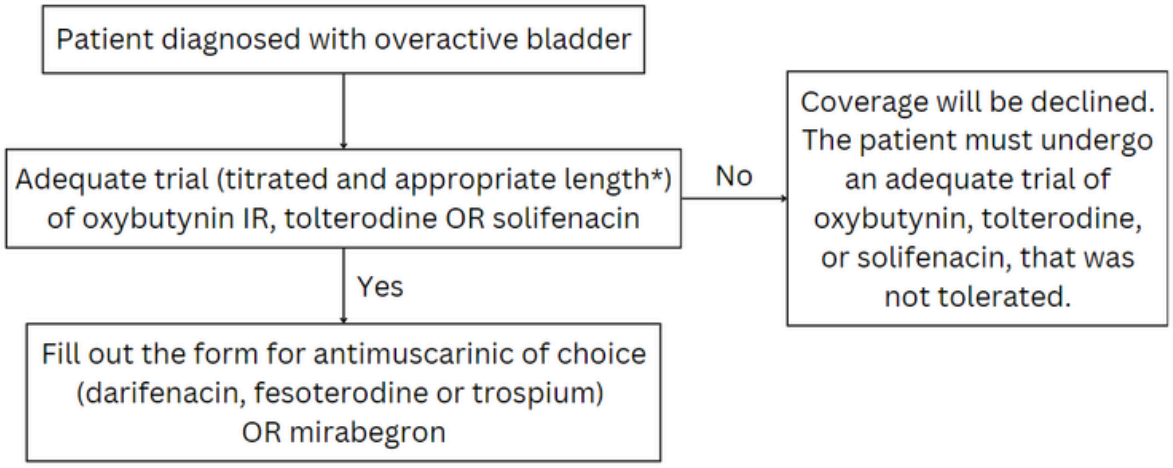
	MEN		
Age (yrs)	Low Risk (<10%)	Moderate Risk (10-20%)	High Risk (>20%)
50	> - 3.4	≤ - 3.4	--
55	> - 3.1	≤ - 3.1	--
60	> - 3.0	≤ - 3.0	--
65	> - 2.7	≤ -2.7	--
70	> - 2.1	- 2.1 to - 3.9	< - 3.9
75	> - 1.5	- 1.5 to - 3.2	< - 3.2
80	> - 1.2	- 1.2 to - 3.0	< - 3.0
85	> - 1.3	- 1.3 to - 3.3	< - 3.3

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special AuthorizationDrug Products. 2025. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Hanley D, Billington E. Osteoporosis. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2018 [updated 2021 May 3 cited 2023 Mar 17]. Available from: http://www.myrxtx.ca.
3. Papaioannou A, Morin S, Cheung A, et al. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. Can. Med. Assoc. J 2010; 182(17) 1864-1873; DOI:10.1503/cmaj.100771.
4. Morin, S.N. et al. (2023) 'Clinical practice guideline for Management of Osteoporosis and Fracture Prevention in Canada: 2023 update', Canadian Medical Association Journal, 195(39). doi:10.1503/cmaj.221647.

OVERACTIVE BLADDER

COVERAGE ALGORITHM: ANTIMUSCARINICS AND BETA-3- ADRENERGIC AGONIST



*Reasonable trial considered to be 12 weeks of duration

TIPS

- Fill out the "Standard Special Authorization Form"
- Include as much information on lack of efficacy or intolerability to previous agents as possible.
- Special authorization may be applied for without an adequate trial of an open-benefit medication if a patient has a contraindication to anticholinergics (such as age, drug interactions, etc.); this will be taken into account if presented on the request.

NLPDP CRITERIA DARIFENACIN, FESOTERODINE, TROSPIUM OR MIRABEGRON:

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

EVIDENCE FOR USE

Antimuscarinics are considered second-line treatment for overactive bladder (urge incontinence) and are the preferred treatment option when nonpharmacologic options fail to provide adequate symptomatic relief. These medications have been shown to increase bladder capacity, improve urge symptoms, enhance quality of life and reduce incontinence episodes up to 50%. However, the clinical significance in some patients may be small.

All antimusarinics are equally effective however, more selective agents (darifenacin, solifenacin, trospium) demonstrate reduced side effects compared with traditional anticholinergic therapy and may improve adherence. Darifenacin is the most M3-selective agent and is thought to have little effect on cognition. However, it tends to be very constipating.

Mirabegron is an alternative to antimuscarinics and is often better tolerated improving adherence. Compared with placebo, mirabegron is effective in reducing the number of incontinence and micturition episodes (about 1 fewer episode of each every 2 days). Given that it is a beta-3 agonist, side effects may include tachycardia and hypertension, in addition to nasopharyngitis and UTIs.

PRODUCT AVAILABILITY

- DARIFENACIN (ENABLEX 7.5mg & 15mg tablet)
- FESOTERODINE FUMARATE (TOVIAZ 4 MG, 8MG TABLET and generics)
- TROSPIUM CHLORIDE (TROSEC 20mg)
- MIRABEGRON (MYRBETRIQ ER 25mg, 50mg TABLET)

RENAL DOSING CONSIDERATIONS

Fesoterodine (Toviaz): limit to 4mg daily if CrCl < 30ml/min
Solifenacin (Vesicare): limit to 5mg daily if CrCl < 30 ml/min
Trospium (Trosec): Do not exceed 20mg at bedtime if CrCl < 30 ml/min

DRUG INTERACTIONS

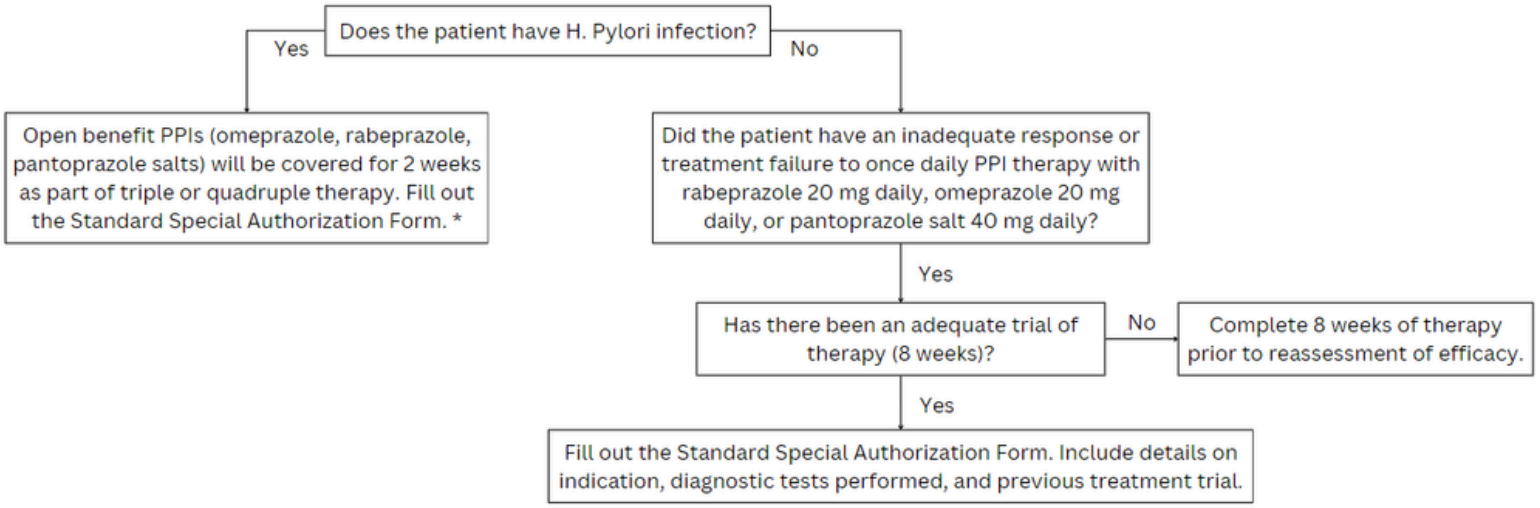
Antimuscarinic agents are extensively metabolized by the CYP isoenzyme system and, as a result, have a number of drug interactions that may require dose adjustments. It is recommended to take a complete history of medication use, including OTC products, natural health products, and vitamins/minerals is reviewed prior to initiating therapy to screen for these types of interactions.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special AuthorizationDrug Products. 2023. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Sadowski, C Urinary Incontinence in Adults. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2018 [updated 2021 April 14 cited 2023 Feb 16]. Available from: http://www.myrxtx.ca. Also available in paper copy from the publisher.

PROTON PUMP INHIBITORS

COVERAGE ALGORITHM: TWICE DAILY PPI COVERAGE (RABEPRAZOLE, OMEPRAZOLE, OR PANTOPRAZOLE)



*Bismuth subsalicylate 262 mg will also receive coverage as part of quadruple therapy for H. pyori.

TIPS

- Fill out the "Standard Special Authorization Form" for BID therapy and document the indication and provide supporting evidence.
- NLPDP will only cover rabeprazole (Pariet), omeprazole (Losec), pantoprazole sodium (Pantoloc) and pantoprazole magnesium (Tecta) as open benefits. NLPDP will not cover dexlansoprazole or esomeprazole at all. Lansoprazole is available through Special Authorization. See next section for details.
- Coverage of the above PPI's is limited to once daily therapy without Special Authorization; twice daily therapy may be covered if there is failure of an adequate trial of once daily therapy (8 weeks). Duration of coverage depends on the indication.
  - Symptomatic GERD or reflux: 8-week approval
  - Erosive, Ulcerative or Barrett's esophagus: long-term approval
  - Peptic Ulcer Disease: 12-week approval
  - Gastroprotection for high-risk patients (such as chronic NSAID use*): 1-year approval with reassessment
    - *This may include patients taking chronic low-dose ASA, if other GI bleed risk factors are present such as if the patient is taking another antiplatelet agent or has a history of GI bleeding.
  - Zollinger-Ellison Syndrome: long-term approval
  - H. Pylori Eradication: 2-week approval (a second treatment will be considered if more than 4 weeks has passed since first eradication attempt AND a different antibiotic regimen is selected. Additional approval beyond this will require diagnostic confirmation of H Pylori presence)

Note: it is important to provide supporting details relevant to coverage to aide in approval, such as:

- Previous agent, dose, duration, and response
- Endoscopy date and results
- NSAID dose and duration
- History of GI bleeds

LANSOPRAZOLE

- In whom there has been therapeutic failure of 8 week trials of regular benefit PPIs* (i.e. omeprazole 20mg, rabeprazole 20mg daily, pantoprazole sodium 40mg daily and pantoprazole magnesium 40mg daily).
  - *Patients must fail all open-benefit PPIs before consideration will be given for lansoprazole coverage.
- When compounded as an oral suspension for patient 12 years and younger, who require the use of a proton pump inhibitor and cannot use a tablet or capsule.
- Clinical Note:
  - Requests for lansoprazole 30mg BID will only be considered if there has been inadequate response to an 8 week trial of lansoprazole 30mg OD dosing for the indications listed above.

EVIDENCE FOR USE

At equivalent doses, available proton pump inhibitors will confer similar symptom relief, and mucosal healing, in addition to having similar tolerability. The choice of a specific PPI is typically determined by patient preference or insurance coverage, as agents of this class are considered equally efficacious in terms of esophagitis healing and symptom resolution.

- PPIs are more effective than H2RAs and relieve symptoms of GERD more rapidly.
- It is recommended to treat moderate to severe GERD (or symptoms occurring >2 times per week) for 8 weeks with once daily PPI therapy.
- It is recommended to empirically treat functional dyspepsia for 4 to 8 weeks with once daily PPI therapy.
- PPIs are prodrugs that require proton pump activation; therefore, they are most effective when administered 30 minutes prior to a meal (preferably breakfast). Dexlansoprazole does not need to be taken before a meal.
- It is recommended to treat H pylori infection with quadruple therapy for 14 days, which includes BID PPI therapy.
- Gastroprotective agents (including standard dose PPIs) should be considered indefinitely for all patients using chronic NSAIDs or ASA who have risk factors for peptic ulcer disease: >65 years of age, multiple or high dose NSAIDs, use of antiplatelets, use of corticosteroids, use of SSRIs, use of anticoagulants, history of GI ulcer, history of upper GI bleeding, or severe comorbidity (example: renal or hepatic failure, COPD, CHF).
- Standard dose PPIs are more effective than standard dose H2RAs and misoprostol 400 mcg daily for the prevention of NSAID-induced GI ulcers.

Long-term use of PPIs (greater than 4 to 8 weeks) is associated with increased risk of side effects (such as diarrhea, impaired vitamin B12 absorption, C difficile infection, hip fractures, pneumonia, and impaired magnesium absorption). PPIs also increase pill burden and have a large economic impact. The Canadian Society of Gastroenterology suggests a trial of deprescribing annually to help individuals stop or reduce the dose of PPIs. This recommendation does not apply to patients with Barrett esophagus, severe esophagitis (grade C or D on endoscopy), a history of GI bleeds, or chronic NSAID use with a risk of bleeding.

REFERENCES

1. Government of Newfoundland Labrador, Health and Community Services: NLPDP. Information on Special Authorization Drug Products. 2022. Accessed from: https://www.gov.nl.ca/hcs/prescription/covered-specialauthdrugs/.
2. Pham C. Dyspepsia and GERD. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2018 Sept 27; cited 2022 Feb 15]. Available from: http://myrxtx.ca. Also available in paper copy from the publisher.
3. Wolfe M. Proton pump inhibitors: Overview of use and adverse effects in the treatment of acid related disorders. In: UpToDate [Internet]. Waltham (MA): Wolters Kluwer Health; c2022 [updated 2021 Nov 29; cited 2022 Feb 25]. Available from: http://www.uptodate.com
4. Targownik L. Dyspepsia and Peptic Ulcer Disease. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c 2016 [updated 2021 Mar 5; cited 2022 Feb 15]. Available from: http://myrxtx.ca. Also available in paper copy from the publisher.
5. Howell P, Pottie K, Thompson W. Deprescribing. In: Therapeutics [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2016 [updated 2021 Apr 1; cited 2022 Feb 15]. Available from: http://myrxtx.ca. Also available in paper copy from the publisher.
6. NHS West Essex Clinical Commissioning Group. Proton Pump Inhibitors (PPIs) and antiplatelet therapy. Advisory guidance on when to initiate a PPI for gastro-protection. [updated 2022 February; cited 2023 July 19]. Available from: https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/clinical-guidelines-and-prescribing-formularies/01-gastro-intestinal-system/3033-ppi-advisory-guidance-on-when-to-iniaite-with-antiplatelet-therapy/file.

SPECIAL AUTHORIZATION OF LIQUID FORMULATIONS

FOR USE IN PATIENTS WHO ARE UNABLE TO SWALLOW CAPSULE/TABLET FORMULATION

- Amlodipine 1 mg/mL solution
- Carbamazepine (Tegretol 20 mg/mL suspension & generics) – For patients who are fed via gastric tube.
- Cephalexin 125mg/5mL and 250mg/5mL oral suspension - For adults (over 13 years of age) who cannot swallow pill form. These requests will be assessed urgently.
- Ciprofloxacin 10g/100mL oral suspension - When oral tablets are not an option. Previous special authorization requirements for ciprofloxacin still apply.
- Fluconazole (Diflucan 50 mg/mL suspension) - For the treatment of oropharyngeal candidiasis when nystatin has failed, or for systemic infections when oral tablets are not an option.
- Fluoxetine 20 mg/5mL liquid
- Lansoprazole – Compounded as an oral suspension for patients 12 years and younger, who require the use of a proton pump inhibitor and cannot use a tablet or capsule. All special authorization criteria from the “Lansoprazole” section must be met.
- Levetiracetam 100 mg/mL solution
- Rivastigmine 2 mg/mL oral solution - For the treatment of patients with mild to moderate dementia who are unable to swallow oral solid dosage forms.
- Valganciclovir (Valcyte 50 mg/mL solution)

TIPS

Use the standard form.