

Understanding Pharmacare 101

This document is written to acquaint you with the Pharmacare process and, in particular, special authority policies relevant to their questionnaire on osteoporosis therapy coverage under Pharmacare.

What is Special Authority?

Special authority is a Pharmacare process where Pharmacare will not fund a physician prescription for an indicated therapy unless particular criteria are met. For most diseases, there are open listed products (often inexpensive generics) as well as more effective but more expensive therapies which are restricted to certain categories of patients.

Where do the Special Authority criteria come from?

This is very difficult to determine. The Drug Benefit Committee are appointed government advisors who advise Pharmacare and likely are the source of the Pharmacare criteria. Frequently, it appears that their decisions and criteria are motivated by savings in the pharmaceutical budget at the expense of costs in the medical care budget, long-term care budget, and detrimental effects on patient health. Physicians expert in the field are seldom consulted. Pharmacare has informed us that their last review of the osteoporosis therapeutic area was based on a document from 2008 (Prolia was first approved in Canada in 2010).

Are there other criteria aside from the published (Pharmacare website) special authority criteria which would allow Pharmacare funding for patients?

Pharmacare is reluctant to publish broader criteria for special authority since this may expand access. Nevertheless, if a physician is aware, there may be other patient criteria which would qualify a patient for a medication. For example, bisphosphonates are contraindicated in patients with kidney failure although there is no Special Authority criteria for Prolia (which has no renal contraindication). Often, but not always, Pharmacare will adjudicate that patients with kidney failure could be funded for Prolia.

Are all Health Canada approved products eligible for Pharmacare coverage?

Frequently there are delays in Pharmacare listing of products even with Special Authority criteria. For example, Forteo (teriparatide brand or generic) has been available for the past 18 years as a Health Canada approved bone building product. This product is not listed with Pharmacare and so there is no access. Similarly, the other bone building medication Evenity (romosozumab) has been Health Canada approved for two years and remains without a Pharmacare listing or Special Authority criteria.

Is there a common standard for approving Pharmacare coverage of medications for different diseases?

As examples, hypertension, hypercholesterolemia, and diabetes are chronic diseases which are common amongst patients and which have both generic and brand therapy options. Generally the older generic

products are “open listing” which means no form needs to be filled by a physician in order to achieve Pharmacare funding for patients. Newer medications have Special Authority criteria to restrict their use, most often intolerance or lack of effectiveness of less expensive medications would allow funding for the more effective and more expensive products. Pharmacare has even taken on monitoring devices and will, with Special Authority criteria, fund continuous blood glucose monitoring for diabetes patients (at a cost of over \$4000 per year).

Does completing the “Your Voice” questionnaire make a difference?

Filling the survey certainly does make a difference. Pharmacare is committed to listening to patients’ opinions about the impact of their disease on their quality of life. Although patients are not expected to analyze the effectiveness of different therapies, Pharmacare is willing to listen to patients who have been denied Pharmacare coverage of treatments that their physician has prescribed.

How long does Pharmacare Special Authority paperwork take to process?

Be prepared to wait at least three months for a response from Pharmacare. In October 2021, Pharmacare technicians are working on June 2021 applications and sometimes applications earlier than this are still stuck in the system. Frequently your physician may have to send back responses to Pharmacare “requests for further information” including documents from your health record. All of this leads to substantial delays.

What are the Special Authority criteria for osteoporosis therapies?

Alendronate, risedronate weekly generic oral bisphosphonate (brand Fosamax, Actonel). Cost \$120 per year.

A physician must fill a Special Authority form stating that a patient has had a clinical (painful) or x-ray proven fragility fracture due to osteoporosis. Patients with low bone density, declining bone density, high calculated fracture risk, other risks such as breast cancer hormone therapy, prostate cancer hormone therapy, prednisone, etc. would not qualify patients for Pharmacare funding.

Zoledronate annual intravenous bisphosphonate infusion (Aclasta). Cost \$360 per year including infusion cost.

A physician must fill a Special Authority form stating that a patient has had an osteoporotic fracture and also has an obstruction to swallowing a pill. Intolerance or ineffectiveness of oral bisphosphonate is not considered a valid criteria for intravenous therapy although we know this may improve patient outcomes in such circumstances.

Denosumab six monthly subcutaneous injections (Prolia). Cost \$800 per year

A physician must fill a Special Authority form stating that a patient has had an osteoporotic fracture and also has either an obstruction to swallowing a pill or an immune mediated hypersensitivity reaction to bisphosphonate. Oral bisphosphonate intolerance, declining BMD, fracture on therapy, kidney failure,

hormone therapy for breast cancer or prostate cancer, etc. are not accepted as Special Authority criteria.

Teriparatide daily injections (Forteo). Cost \$8000 per year for two years.

Special Authority is not available and the only patients who can have this therapy are those who can cash pay or have an extended medical benefit (such as our Ministry of Health colleagues, politicians, etc.).

Romosozumab monthly injections (Evenity). Cost \$8000 per year for one year.

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How do I fill out the Pharmacare “Your Voice” questionnaire?

Pharmacare is not expecting patients to have knowledge of the relative effectiveness of osteoporosis therapies and their application to particular patients. What they would like to hear is the impact of osteoporosis on patients’ quality of life. They also need to hear about frustrations with the current Pharmacare Special Authority system. They would need to hear from patients that the product chosen by their clinician as being best for their health status was not supported by Pharmacare.

Describe how osteoporosis affects your day-to-day life? What overall improvements do you expect your treatments to provide?

Here Pharmacare wishes to hear that your quality of life has been negatively impacted by osteoporosis and/or fractures. You can relate both symptoms from the fracture itself (back pain, pain and disability while the fracture is healing), as well as long-term issues such as restricted movement of the joint after fracture, prolonged pain after a fracture, fear of fracture, limited mobility, requirement to use canes or walking aids. You can also include information about the need for caregivers to provide support or your need to move to assisted living or nursing home care.

Tell us about your experience with each of these drugs specifically. Was the treatment successful or unsuccessful, and why?

Pharmacare is asking what medications you may have tried and what your criteria are for judging the medication. This is a good place to tell them about side effects from medication which have led to intolerance (for example stomach upset on oral bisphosphonate). You can also tell them about freedom from fragility fractures that can occur in patients on effective therapy. In addition, they may benefit from hearing about improvements in bone density on treatment. If you have not been eligible for a Pharmacare funded product, this would be a good place to explain that treatment funded by Pharmacare has not been available.

Did you experience any challenges using the drug(s) or any bad side effects?

Certainly, you can tell them about side effects of medications here but also challenges. There is no question asking about effectiveness of therapy and so this can provide you an opportunity to reinforce your comments in the prior section about treatment effectiveness. Many patients feel that Pharmacare access and Special Authority paperwork is a major challenge to achieving effective osteoporosis therapy.

The above two questions are repeated for the other osteoporosis therapies under review. Be sure to elaborate challenges with achieving care for osteoporosis pharmaceuticals in addition to the side effects question which they directly ask.

Has PharmaCare coverage of certain drugs, or coverage limits (e.g., limits to the duration of coverage or the maximum dosage) affected your choice of medication? If so, how?

This is a very broad question asking for comment on Pharmacare policies with regards to osteoporosis medications. Please read over the Special Authority criteria earlier in this document and comment on any limitations or compromises to your care which you or your physician have had based on Pharmacare Special Authority criteria. This question allows both comments from people who are on osteoporosis therapy and from those who are not on osteoporosis treatment because of lack of coverage or intolerance of Pharmacare funded therapies. Many patients intolerant of oral bisphosphonate therapy are required to take other stomach acid reducing treatments in order to tolerate the Pharmacare funded product. Patients with absorption problems (most likely leading to lack of effectiveness of oral bisphosphonates) are excluded from non-oral therapies such as intravenous zoledronate or subcutaneous denosumab.

Are there any additional factors you would like PharmaCare to consider during its review of drugs used for the primary prevention of osteoporosis?

Here you can expand on any areas not covered by prior questions. You may feel that a patient with a bone density T score of -3.5 but no fracture should not be excluded from osteoporosis treatments funded by Pharmacare. You may feel that a patient with a high fracture risk (FRAX calculation), requiring treatment by all of our osteoporosis guidelines, cannot achieve funding for any osteoporosis treatment through Pharmacare. You may feel that Pharmacare criteria need to be more evidenced based and in line with national and international osteoporosis care guidelines. You may feel that external review of Pharmacare policies and greater transparency in the development and implementation of Special Authority criteria would benefit patients. You may feel that your physician's opinion regarding the best medication for your condition should be more relevant than a Pharmacare technician deciding whether your medication will be funded or not. You may wish to inquire as to why access to osteoporosis pharmaceuticals is the most restrictive in British Columbia as compared to any other provinces. You may wish to thank Pharmacare for the opportunity to express your opinions and to incorporate these thoughts into their upcoming review.