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Global Healthy Living Foundation Australia and CreakyJoints Australia

Submission to support the listing of Romosozumab (Evenity®) on the PBS for the treatment of osteoporosis

For consideration at the March 2023 PBAC Meeting

These comments are submitted by CreakyJoints Australia and Global Healthy Living Foundation Australia (GHLF Australia) on behalf of our patient community. We appreciate the opportunity to provide this submission.

PBAC public consultation survey

Q1: Please outline your experience with the medical/health condition

CreakyJoints Australia/GHLF Australia

About us

GHLF Australia is part of the US-based Global Healthy Living Foundation (GHLF), a non-profit organisation whose mission is to improve the quality of life for people with chronic illness. GHLF Australia is the parent organisation of CreakyJoints Australia, the vibrant online patient community for autoimmune and inflammatory arthritis patients and their families throughout Australia.

GHLF Australia aims to localise, mobilise and engage the Australian patient and caregiver community and to provide education, advocacy and research for better health outcomes.

Osteoporosis and comorbidities

11.5 per cent of Australians with arthritis also have osteoporosis although the exact link between the conditions varies based on arthritis type.

Research suggests that both osteoporosis and osteoarthritis can lead to increased pain, disruptions in social life and overall reduced quality of life.

Osteoporosis is thought to occur in patients with ankylosing spondylitis (autoimmune arthritis of the spine and pelvis) for a variety of reasons, according to a recent study in Frontiers in Medicine. This includes limited spinal mobility, increased pro-inflammatory cytokine levels, physical inactivity and malabsorption for patients who also have inflammatory bowel disease.

Complicating the risk in this population is that traditional ways of measuring bone loss, such as bone density scans, are less reliable in people with ankylosing spondylitis (AS). This is because patients with AS get more calcium deposits in more places in their spine which can make DEXA scans (x-ray scans used for bone density screening) uninterpretable.

While more research is needed, the same trinity of risk factors applies to those with psoriatic arthritis (PsA), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE):

- **Chronic inflammation**: People with chronic inflammatory diseases often have systemic inflammation, which is associated with generalised bone loss.
- **Corticosteroid drug use**: One of the biggest reasons someone with inflammatory arthritis is at a higher risk of osteoporosis is taking corticosteroid medication, such as prednisolone, to manage symptoms. With RA in particular, research has found that the combination of inflammation, along with corticosteroid medications (which are often used to control a flare), can negatively impact bone mineral density, increasing the risk of bone fracture and osteoporosis.
- **Inactivity:** Inflammatory arthritis can cause pain, fatigue and stiffness, which can make regular exercise a challenge.

In addition, both rheumatoid arthritis and SLE are more common in women who have the greatest risk for osteoporosis — 1 in 3 women over the age of 50 years (versus 1 in 5 men) will experience osteoporotic fractures in their lifetime.

We have anecdotal evidence that many of the people with arthritis in our CreakyJoints Australia community also have osteoporosis. Some have told us they developed OP after prolonged use of prednisolone yet, overall, there is a lack of awareness of OP risk within the arthritis community.

Some of the reasons people are not aware of their OP risk include:

- Having the false belief that it only occurs in older adults.
- The fact that OP is usually asymptomatic until fractures start to occur.
- Not being informed that OP can be a comorbidity related to their primary health condition.

Q2: How is the medical/health condition currently treated?

CreakyJoints Australia/GHLF Australia

Osteoporosis is largely a preventable disease. However, given that many people in our community aren't aware they have OP until they have a fracture, the condition is undertreated and underdiagnosed.

In Australia, OP is initially treated with antiresorptive therapy (ART) or other therapies that slow down the natural bone density loss process (including menopausal hormone therapy and selective oestrogen receptor modulators). These medicines improve bone mineral density and reduce the risk of fractures.

Some OP treatments are only prescribed for women around the time of menopause or after menopause as they act on female hormones. Therefore, men (or women who have not reached menopause) with OP have even fewer treatment options than older women.

Currently, only those who meet very strict criteria determined by the time they have been on first-line treatment, their bone mineral density and the number of fractures they have had (at least two) can qualify for a second line of treatment with a bone-building (anabolic) drug such as romosozumab.

GHLF and GHLF Australia are developing a Global Bone Advocacy Program entitled “Strong Bones and Me” to implement patient-centred education, awareness and engagement on bone health and osteoporosis (OP) that patient groups and organisations can provide to their communities. The content will focus especially on osteoporosis in relation to patients’ existing disease state(s) and/or comorbidities.

This program will not only include the global arthritis community, but it will also address OP risks of comorbidity with other conditions, such as cancer, diabetes, heart conditions and more.

Comments from our community

“The main treatment, medication-wise, for osteoporosis is a six-monthly injection of Prolia. There has been little research done on people who have been on Prolia for more than 10 years. This isn't generally a big problem, because most people aren't diagnosed with osteoporosis until they are in their 70s. I am facing a challenge and a visit to an endocrinologist who specialises in bone health after August 2023.

I was diagnosed with osteoporosis in 2008, with subsequent multiple fractures around 2012/13. My rheumatologist then put me on Prolia but those 10 years will come to an end while I am in my 50s. There is another treatment that I satisfy the requirements for, as far as the number of fractures I have had, but not now as far as my bone density is concerned. This is because I have been on Prolia, which has increased my bone density.

I am glad that I don't qualify for that drug because it carries with it a small increased risk of bone cancer, so I didn't want to take it anyway. However, if I go off Prolia suddenly my bone density is known to take a nose-dive down back to osteoporosis and fractures. This means that I have that appointment with the endocrinologist, after my August Prolia injection, to find out where I go from there.”

Anonymous comment from the CreakyJoints Australia mini-survey on osteoporosis and arthritis.

Q3: What do you see as the advantages of this proposed medicine, in particular for those with the medical condition and/or family and carers?

CreakyJoints Australia/GHLF Australia

Romosozumab (Evenity®) is the only osteoporosis treatment that both increases bone formation and decreases bone resorption. It is a biologic therapy administered by subcutaneous injection once per month for 12 months, followed by regular, ongoing treatment with an antiresorptive drug.

The sponsors of romosozumab now have strong clinical evidence showing that anabolic therapy leads to faster and more effective protection from fractures than ART and that the anabolic effect on bone mass and skeletal structure is most pronounced when used as a first-line treatment. We believe romosozumab should be available as a first-line treatment for those with a high and imminent risk of fractures for this reason.

We also support the sponsor’s call to expand the access criteria for romosozumab as a second-line treatment as this would allow those who are just outside the current prerequisites to access this, potentially life-changing, treatment.

Romosozumab (as a first or second-line treatment) could help many people in our community who live with arthritis and related conditions. For example, for someone already dealing with severe pain from arthritis getting a fracture from OP could make their pain levels even more debilitating. Also, improved

bone mass is very important for people with musculoskeletal conditions as it helps them sustain a physically active life to manage their condition. For those needing to undergo orthopaedic surgery due to their arthritis, improving bone density is especially important.

Making romosozumab more widely available would also benefit the government and the broader community as the costs associated with treating osteoporosis-related fractures would likely decrease significantly.

Q4: What do you see as the main disadvantages of this proposed medicine?

CreakyJoints Australia/GHLF Australia

Romosozumab can currently only be prescribed by a specialist, whereas other first-line OP treatments can be prescribed by GPs.

Romosozumab has not been tested in pregnant women and it is not known whether it passes into breast milk. Therefore, women of childbearing age with OP cannot safely use this treatment.

There is no information on the effects of using romosozumab with alcohol so this could be a risk factor for some people.

During the clinical trial stage, some people experienced cardiovascular issues (such as a heart attack or stroke). It is not yet known if this was a coincidence or if romosozumab was the cause. Therefore, those with pre-existing cardiovascular issues may need to discuss their risks versus benefits with their treating doctor before starting treatment with romosozumab.

Q5: Please provide any additional comments you would like the PBAC to consider.

CreakyJoints Australia/GHLF Australia

We have no additional comments to make.

Q6: We are considering revising the consultation survey for future PBAC consultation rounds, along with providing additional guidance. Are there any suggestions you would like us to consider as part of this process?

CreakyJoints Australia/GHLF Australia

It would be helpful to have the option to provide input for more than one medicine in a single submission. This would be especially beneficial in cases where similar amendments are proposed for multiple medicines in one disease area.

Sources

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