PRADER-WILLI SYNDROME ASSOCIATION NEW ZEALAND
ADVOCACY · EDUCATION · SUPPORT

21.11.2023

Pharmac, Te Pātaka Whaioranga
Via email: consult@pharmac.govt.nz

Re. Proposal to fund testosterone gel and to award Principal Supply Status to Testogel

The Prader-Willi Syndrome Association is not opposed to the widening of testosterone treatment types by including a gel option. However, we would like Pharmac to ensure that a tablet / capsule form of testosterone remains available.

Our reasons for requesting a continuation of a capsule form of testosterone are:

a. Testosterone patches and gel may be unsuitable for some people with PWS who experience a higher level of sensory issues.

b. Testosterone patches and gel can cause skin irritation issues which can lead to skin picking, a common behavioural symptom of PWS. Skin picking can become severe and lead to serious infections.

c. Testosterone injections are unsuitable for some people living with PWS due to mood stability issues being exacerbated by peak highs and troughs of hormone levels. Some families have reported cases of increased aggression. Families also worry that injectable testosterone does not allow for stopping treatment quickly if behavioural problems do occur, and it is therefore recommended by experienced clinicians to initiate treatment in PWS patients with a daily, low dose alternative.

d. The application of testosterone gel may cause issues of transmissibility if it needs to be applied by someone else, which is quite likely in patients with PWS and intellectual disability. For adults who live in supported living residential environments, the application of gel by non-medically trained support staff also raises concerns around safety, appropriateness, and privacy.

We understand that Andriol capsules have been discontinued and replaced with Steril-Gene brand under section 29, and that this is now limited to those who were prescribed an oral testosterone treatment before 1 November 2021.

We would like to know why a tablet / capsule form of testosterone is not an available option to new patients starting testosterone treatment?

If the subsidy by endorsement restriction is possibly due to rules under section 29 of the Medicines Act 1981, Pharmac needs to be working to secure an approved replacement for Andriol which would not need to comply with section 29 regulations.

If there are no such rules that prohibit prescribing to new patients under section 29, we do not understand the reason for the restriction. The reason given for Andriol being discontinued was that the supplier (Merck Sharpe & Dohme) discontinued supply. Pharmac's Nov 2022 RFP states that a prescribing restriction was put in place for capsules due to the supply issues of this continuation. We can understand this when Andriol was the sole supply, but with the availability of a new brand (Steril-Gene), we do not understand why the restriction is still in place? Further clarity is needed around the reasons for the change to subsidy by endorsement for testosterone undecanoate.

We are aware that testosterone gel may have a lower cost than testosterone capsules and hope that the prescribing change for capsules is not due to budget constraints and a preference to phase out the availability of a capsule form in favour of a gel form.

Due to concerns about an unapproved medicine being supplied to patients with PWS, some of whom may not understand its unapproved status, we have sought information from Medsafe about Steril-Gene's safety profile and the reasons for it not being approved. Their response was that Medsafe have not received an application for Steril-Gene and therefore, Medsafe holds no formal data relating to the quality, safety, and effectiveness of this product.
It is reassuring to know that an application for approval has not been declined and there does not appear to be any known safety concerns specific to the Steril-Gene brand.

Therefore, in summary, we do not object to the funding of testosterone gel as an additional option for other patient groups who may find it more suitable, but we would like Pharmac to ensure that Steril-Gene or an alternative capsule brand (preferably Medsafe approved) are continued without restriction, i.e. made available to new patients needing testosterone treatment. If section 19 of the Medicines Act does not allow this, an application for Steril-Gene needs to be received by Medsafe for approval, or Steril-Gene needs to be replaced by an approved testosterone tablet / capsule as soon as possible.
This would provide for an appropriate range of non-injectable testosterone presentation forms to ensure there is sufficient variety to meet the health needs of patients.

Yours sincerely,

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