Proposal to list Benzathine Penicillin G on the Pharmaceutical Benefits Scheme Prescriber Bag List

1. SUMMARY

There is an ongoing outbreak of infectious syphilis across northern Australia.¹ Listing benzathine penicillin G (BPG) on the 'Prescriber Bag', also known as emergency drug supply (EDS), would provide a mechanism to reduce time to treatment and loss to follow-up for infectious syphilis as one important measure to address this outbreak. Treatment of infectious syphilis is of significant public health importance to Australian governments.² The net cost of EDS listing only relates to non-remote BPG supply, which is very small compared to remote use. Below, we explain how this cost will be insignificant in the context of overall PBS and remote BPG spending and the current national Syphilis Enhanced Response. We propose that this subsidy will result in cost savings by improving the effectiveness and equity of care, and by reducing waste. Listing BPG on the EDS is entirely within the current PBS EDS criteria.

2. BACKGROUND

There were 4,398 cases of infectious syphilis were notified in 2017, with 18% of cases in the Aboriginal and Torres Strait Islander population. The early detection and treatment of syphilis is a priority under the National Blood Borne Virus and Sexually Transmissible Infectious Strategy.² Early treatment of syphilis is vital to prevent onward transmission to sexual partners. Urgent treatment is required in the case of pregnancy to prevent congenital syphilis occurring in utero.

BPG is listed in the Australian Therapeutic Guidelines: Antibiotic for the treatment of syphilis and the secondary prophylaxis of rheumatic heart disease (RHD).³ While BPG is also used in some rural and remote Aboriginal communities for bacterial skin infections this is likely to comprise a small proportion of total use.⁴

BPG is currently listed on the PBS general schedule without any restrictions on its use. While it is listed under both 2267H (medical and nurse practitioner) and 5027N (dental) over 95% of use is under the medical/nurse practitioner code. Because BPG is listed on the PBS with no Restrictions or Authority, listing BPG on the Aboriginal and Torres Strait Islander PBS list would not provide any additional benefit to patients or practitioners.

Syphilis disproportionately affects Aboriginal and Torres Strait Islander people and gay and other men who have sex with men. While current arrangements ensure access to early treatments in remote areas this is not the case for urban and non-remote rural locations. Listing on the EDS would improve the equity of access to early treatment.

3. RATIONALE AND BENEFITS OF EDS LISTING

Listing on the EDS would provide a mechanism for non-remote Aboriginal health services and general practitioners to either stock BPG or alternatively obtain supply for a patient in advance of a consultation. Practitioners regularly treating syphilis may choose to stock BPG: this would reduce time to treatment and loss to follow-up for a serious disease of significant public health significance.

Alternatively, practitioners diagnosing a case of syphilis would be able to obtain a supply of BPG under EDS before the patient returns, again reducing time to treatment. In the expert opinion of sexual health physicians this is particularly likely to be of benefit when follow-up has proven difficult, especially in pregnant women, where urgent treatment is recommended.⁵

The use of BPG in EDS is consistent with other current EDS items and associated indications, and subsidy of BPG satisfies EDS criteria, including "to provide prescribers with medicines for immediate administration without charge to the prescriber or the patient".

Supply of BPG through EDS in remote s100 RAAHS areas for any indication is not necessary, due to the bulk supplies of BPG already available through this scheme. Therefore, BPG EDS supply only relates to non-remote health services.

3.1. Cost considerations

Total cost related to EDS subsidy for the Commonwealth Department of Health is unlikely to change significantly, and may be reduced. Cost changes will be relatively immaterial in the context of both the s100 Remote Area Aboriginal Health Services Scheme (s100 RAAHS) BPG spending and the current national syphilis response, and will largely relate to the movement between federal funding streams. Below, we present data to illustrate approximate costs involved and the proposed savings with the data we have available. It is not intended to be an exact forecast but will provide adequate insight into the scope of costs.

BPG requires a large bolus intramuscular injection and it is not recommended for any conditions other than syphilis or RHD. Peer-reviewed research from the Northern Territory suggests that approximately 95% of national BPG use is for RHD. The research also indicates that the majority of total national BPG use occurs within s100 RAAHS sites.⁶

NACCHO has obtained annual BPG data from 3 large non-remote Aboriginal health services.⁷ This includes prescription data for 4,500 vials ; a significant sample that is approximately 10% of total national non-remote BPG use. These data show that non-remote BPG supply for syphilis account for only around one quarter of total non-remote BPG use.

BPG costs approximately \$300 per Original Pack of 10 or \$30 per 1 vial for injection.⁸ 2015 PBS data indicate that approximately 40,000 vials of BPG were supplied through the PBS (this is excluding s100 RAAHS use). This equates to 4,000 Original Packs of 10 vials. Using the data above, we therefore propose that the total annual Commonwealth cost of BPG for syphilis to be around \$300,000 (one quarter of \$300 x 4,000).

PBS Co-payment data roughly corroborate this. In FY2017-18, the total benefit paid by PBS for nonremote BPG was \$516,918 for General and \$574,853 for Concession. This equates to around 3,600 BPG Original Packs of 10 dispensed through the PBS, which is in the vicinity on the 4,500 referenced above. PBS Safety Net benefits may account for some of this discrepancy.

3.2. Original Pack wastage

BPG is supplied by the manufacturer in packs of 10 vials, while only 2 vials are required to treat infectious syphilis. Data from NACCHO indicates that the vast majority of BPG scripts were supplied at the full Dispensed Price for Maximum Quantity (DPMQ) – i.e. a pack of 10. This quantity is often automatically prescribed as the maximum PBS quantity through Clinical Information Software. Pharmacies also prefer to dispense 10 units to avoid retaining a 'broken' pack, which may be difficult to re-dispense and is at risk of expiring. Under PBS law, an Original Pack of 10 can only be used for the individual 'prescribee'. As the treatment is often once-off, the remaining 8 units must then be discarded. While there is no data related to how many partially used BPG packs are currently being discarded, converse to the current PBS arrangement, one Original Pack of an EDS supply can be used more efficiently for multiple patients on different occasions.

3.3. Patient co-payments

BPG supplied under the PBS attracts a patient co-payment but the loss of patient co-payments is relatively insignificant and offset by savings. According to the FY2017-18 PBS benefits data discussed above, if around 3,600 BPG Original Packs are supplied through General and Concession scripts this would attract co-payments of only \$83,614.⁹ If only one quarter of the use BPG is for syphilis (as per NACCHO data) this means the national annual syphilis co-payment is only around \$20,000. This is nominal figure in PBS terms and is likely to be an overestimate as many co-payments would be exempt or reduced under the Close the Gap PBS Co-payment measure.

3.4. Jurisdictional considerations

State government funded sexual health services diagnose and treat around 25% of infectious syphilis cases.¹⁰ State government services, outside of those covered by the s100 scheme, are unlikely to contribute significantly to BPG use for RHD. As there were 4398 cases of infectious syphilis diagnosed in Australia in 2017, the estimated maximum potential for cost shifting is approximately 1,000 vials or \$30,000 at DPMQ. This is likely to be a significant overestimate as 1) any use diversion to the public sector is likely to result use of the full Original Pack with 5 patients treated per pack and 2) public clinics are unlikely to have the systems to pay private pharmacies to supply routinely stocked medicines.

3.5. Other Commonwealth, patient and systems savings

As increasing the early detection and treatment of syphilis with BPG is a major component of both the National STI strategy² and the Commonwealth Government Enhanced Syphilis Response¹¹, any increased uptake of BPG administration as part of EDS listing is likely to produce net savings.

Supply from the EDS would potentially save 1 short consultation fee per treatment as the current PBS listing requires people to return for administration of treatment after obtaining a prescription.

While the Administration, Handling and Infrastructure fee (AHI fee) is identical for EDS and for patient PBS prescriptions, the EDS distributes AHI across multiple patients and is therefore more efficient.

One ACCHO has reported a patient burden of approximately half to one hour to take the prescription to a pharmacy and then return for a second appointment with the health service. As discussed above, there is also a risk of loss to follow-up when an extra step is required to receive care. Early treatment of syphilis would likely reduce transmission of syphilis and hence reduce health system costs associated with these additional cases.

There is an inherent Commonwealth price ceiling on EDS items due to the limits on quantity and frequency that prescribers can order EDS items. Though currently EDS items do not have PBS Notes, Restrictions or Authorities, PBAC could consider recommending such criteria to be embedded within the EDS listing to reduce use that may be associated with other indications such as RHD.

REFERENCES

- ¹ Commonwealth Department of Health. 2019. Infectious Syphilis Outbreak. Updated 18 March 2019. Accessed at <u>http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-infectious-syphilis-outbreak.htm</u> ² National Blood Borne Viruses and Sexually Transmissible Infections Strategies 2018-2022
- (http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1)

⁴ Personal communication: J. Davis, President, Australian Society for Infectious Diseases and Menzies School of Health Research

⁶ Wyber R, Johnson TD, Patel B. Supply of benzathine penicillin G: the 20-year experience in Australia. Australian and New Zealand journal of public health. 2015 Dec;39(6):506-8.

⁷ Personal communication: M. Stephens, Medicines Policy and Programs, NACCHO

⁸ Dispensed Price for Maximum Quantity (DPMQ) of \$298.51

⁹ = Total benefit paid divided by DPMQ cost, for General and for Concession co-payments

¹⁰ Bourne C, Allen D, Brown K, Davies SC, McNulty A, Smith DE, O'Connor CC, Couldwell D, Jackson E, Bolton M, Rodgers C. What proportion of sexually transmissible infections and HIV are diagnosed in New South Wales' public sexual health services compared with other services?. Sexual health. 2013 May 3;10(2):119-23.

¹¹ Australian Health Protection Principal Committee Governance Group. Enhanced response to addressing sexually transmissible infections (and blood borne viruses) in Indigenous populations. Accessed at

https://www.health.gov.au/internet/main/publishing.nsf/Content/71E8A32E7518E532CA25801A0009A217/\$File/Action-Plan-May18.pdf.

³ Therapeutic Guidelines: Antibiotic, version 15, 2014. Therapeutic Guidelines Ltd. 2014.

⁵ Personal communication: C. Bourne, NSW STI Programs Unit