

February 23rd, 2024

Re: HTA Review Policy and Methods Review | Options Paper | Consultation 2

Dear HTA Secretariat,

We are writing on behalf of Myeloma Australia, the only organisation in Australia dedicated solely to people living with multiple myeloma.

Our role in this review is to amplify the voices of our patient community, highlight the expertise from our Medical and Scientific Advisory Group (MSAG) and share our first-hand knowledge of dealing with the Health Technology Assessment (HTA) system on behalf of our community. We are deeply committed to engaging with and improving HTA processes in Australia.

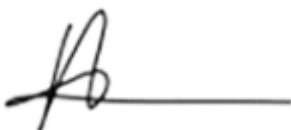
Annually, we provide and facilitate numerous submissions to the Australian HTA system. We have contributed to every stage of the HTA review process and regularly communicate with the Pharmaceutical Benefits Advisory Committee (PBAC), Medical Services Advisory Committee (MSAC), Drug Utilisation Sub-Committee (DUSC), and Therapeutic Goods Administration (TGA). We regularly collaborate with other consumer advocacy groups on common issues and work together with our MSAG to respond to urgent situations such as the COVID-19 pandemic response to ensure the myeloma community are adequately supported and informed. Additionally, we engage with the international HTA community to ensure effective collaboration with all HTA stakeholders. Our dedication to improving and participating in this process is unwavering.

Our options paper submission addresses three key points:

1. **Support for Crucial Elements of the Options Paper:** We endorse and support the process changes outlined in the options paper. Changes such as a single unified entry point, optimised stakeholder engagement practices, individual disease models and improved collaboration with states/territories will make a marked impact on our community.
2. **Concerns Arising from the Options Paper:** However, we wish to highlight certain concerns that have emerged from our review of the options paper. Particularly the lack options for streamlined pathways to submission, proactive inclusion of stakeholders, funding stakeholder participation to ensure equity, Project Orbis mechanisms and the right of reply for clinical experts and consumers. These concerns require careful consideration to ensure the effectiveness and inclusivity of proposed system.
3. **Suggestions and Solutions** We invite the HTA team to partner with us to shape the system and achieve the best, timely decisions for all Australians.

Myeloma Australia and our MSAG are committed to developing comprehensive, sustainable policies that enhance myeloma treatment and care across Australia.

Sincerely,



Mark Henderson
Myeloma Australia CEO



Professor Simon Harrison
Chair, Myeloma Australia's MSAG

Health Technology Assessment Policy and Methods Review - Consultation 2

Response to the HTA Options Paper from Myeloma Australia and our Medical and Scientific Advisory Group (MSAG)

23rd February 2024

Our options paper submission addresses three key points:

1. **Support for Crucial Elements of the Options Paper**
 2. **Concerns Arising from the Options Paper**
 3. **Suggestions and Solutions**
-

Response to the HTA Options Paper from Myeloma Australia and our Medical and Scientific Advisory Group (MSAG)

1. **Support for Crucial Elements of the Options Paper**

We endorse and support critical matters outlined in the options paper. Especially:

- (I) A single unified entry point to the HTA system
- (II) Optimised stakeholder engagement and transparency practices
- (III) Disease-specific models
- (IV) Improved collaboration with states/territories
- (V) Bridging funding

The options paper demonstrates that the voice of the community has truly been heard and we thank the committee. However, despite the length and breadth of this options paper we really need more information about the implementation. We will continue to engage with this process and offer to be part of this going forwards (see 3. Suggestions and Solutions).

2. **Concerns Arising from the Options Paper**

We wish to highlight concerns that have emerged from our review of the options paper. The following were not emphasised and we see them as essential to equity and to facilitate optimal, timely HTA decisions for people living with myeloma.

- (I) Streamlined pathways to submission

The pathways to submission must possess the flexibility to accommodate various scenarios, including the consideration of combined drug/technology proposals, repurposing already approved medicines, submissions by non-industry sponsors, combination therapies, and approvals across different disease areas. An example of this innovation was *1562 – Streamlining Medicare Benefits Schedule Items for Positron Emission Tomography (PET) Project*, this pathway was worlds apart from the way the system often functions, and we hope these methods will be replicated and expanded.

(II) Proactive inclusion of stakeholders

The unified system entry should be accompanied by a proactive communication strategy that educates stakeholders to effectively engage with the system. Invitations to consumers and experts to participate, consult and engage must begin as a priority and continue across the scope of HTA. We must move away from a system that is so inaccessible as to act as a deterrent.

(I) Funding stakeholder participation to ensure equity

If consumer engagement is legislated and valuable it must be adequately resourced. Our organisation invests hundreds of hours per year providing expert clinical information and facilitating consumer engagement (for nil compensation). We do not have a commercial incentive, nor government support. We rely on the generosity of our donors and volunteer hours to make these contributions. This is not a sustainable model.

(II) Project Orbis mechanisms

Myeloma Australia's MSAG strongly supports the principles of Project Orbis and highlights the example of the rapid time to market for Daratumumab in AL amyloidosis following use of the Project Orbis mechanism. By facilitating simultaneous review and approval of cancer therapies across multiple jurisdictions, Project Orbis aims to expedite patients' access to innovative treatments while maintaining stringent safety and efficacy standards. This initiative fosters global cooperation among regulatory authorities, enabling timely access to potentially life-saving therapies. These mechanisms should be integrated into the Australian model.

(III) Right of reply

Currently the appeals process is only accessible to industry sponsors. There is no process allowing disease experts to provide feedback (for example on the interpretation of clinical data) and consumers to report the impact of a decision. This could be factored into the stakeholder engagement piece and facilitated by the unified entry point to the HTA system.

3. Suggestions and Solutions

We invite collaboration and propose the following initiatives:

(I) Partner with our Medical Scientific Advisory Group (MSAG) to develop a disease-specific model tailored to myeloma and leverage the highest quality Real-World Data (RWD) available from the Myeloma and Related Disease and Registry (MRDR). By working together, we can ensure that the evaluation and decision-making processes are informed by comprehensive, disease-specific insights, proactively identifying areas of unmet need and ultimately optimising treatment access and outcomes for myeloma patients.

(II) Collaborate with patient representative organisations such as Myeloma Australia to implement the stakeholder engagement, design the consumer interface of the HTA system and learn from our experiences educating and engaging patients in HTA processes. With adequate resourcing we can empower patients, caregivers and clinical experts with the knowledge and resources needed to navigate the complexities of HTA, so they can contribute, advocate effectively and enable the best, timely decisions for all Australians.
