



FAMILY OF COMPANIES

**IHPA Pricing Framework for Australian
Public Hospital Services 2021-22
Response to consultation**

**SUBMISSION
October 2020**

Company Overview

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Type of Organisation:

Proprietary Limited Company

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Janssen Pharmaceutical is a subsidiary of Johnson & Johnson, the world's most comprehensive and broadly-based healthcare company. In Australia we provide products and services including pharmaceuticals, medical devices, diagnostics and consumer healthcare products.

The Johnson & Johnson Family of Companies in Australia consists of:

- Janssen-Cilag Pty Limited – pharmaceuticals;
- Johnson & Johnson Medical Pty Limited – medical devices and related technology;
- Johnson & Johnson Pacific Pty Limited – consumer health brands.

We employ approximately 1,500 Australians who bring innovative ideas, products and services to advance the health and well-being of the patients we serve. We recognise the impact of serious conditions on people's lives, and we aim to empower people through disease awareness, education and access to quality care. Our research and development focus on identifying medical needs and harnessing the best science, whether from our own laboratories or through strategic relationships and collaborations.

Johnson & Johnson Medical Devices Companies is the world's most comprehensive medical devices business, building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With an unparalleled breadth, depth and reach across surgery, orthopaedics, vision and interventional solutions, Johnson & Johnson Medical Devices Companies are working to profoundly change the way care is delivered.

About the Janssen Pharmaceutical Companies of Johnson & Johnson At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Johnson & Johnson Pacific is the largest over the counter supplier to retail pharmacy in Australia, and one of the top five health and beauty suppliers to Australian grocery. Many of our products are household names and are found in 7 out of every 10 Australian households. Our brands bring value to people's daily lives, while our innovation in areas such as smoking cessation and sun protection are helping to advance the prevention of disease in the Australian population.

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Comments on IHPA Pricing Framework 2021-22

Johnson and Johnson welcome the opportunity to provide comments on IHPAs “Consultation Paper on the Pricing Framework for Australian Public Hospital Services 2021-22”.

Johnson and Johnson is developing new high cost, highly specialised therapies that will be impacted by the Addendum to the National Health Reform Agreement 2020-25. Specifically, our products will be affected by Clauses C11 and C12 of the Addendum that contain specific arrangements for new high cost, highly specialised therapies recommended for delivery in public hospital by the Medical Services Advisory Committee (MSAC).

Johnson and Johnson is developing JNJ-4528 (LCAR-B38M) which is an investigational chimeric antigen receptor T cell (CAR-T) therapy for the treatment of patients with relapsed or refractory multiple myeloma. CAR-T are a cell therapy, which is a form of immunotherapy that uses specially altered T cells to directly and precisely target cancer cells. CAR-T cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient’s own immune system.¹ The Janssen CAR-T design of JNJ-4528 comprises a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies². BCMA is a protein that is highly expressed on myeloma cells.³

Multiple myeloma (MM) is a blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells. In Australia, more than 2,000 people were diagnosed with MM in 2019, and 1,062 estimated deaths from MM⁴. Around 50 percent of newly diagnosed patients do not reach five-year survival.

Although treatment may result in remission, unfortunately patients will most likely relapse as there is currently no cure. Refractory MM is when a patient’s disease progresses within 60 days of their last therapy. Relapsed cancer is when the disease has returned after a period of initial, partial or complete remission. While some patients with MM have no symptoms at all, others are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections. Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and require new therapies for continued disease control.

As part of Clauses C11 and C12 of the Addendum, the arrangements include:

- The Commonwealth will provide a contribution of 50 per cent of the growth in the efficient price or cost (including ancillary services), instead of 45 per cent.
- They will be exempt from the national funding cap for a period of two years from the commencement of service delivery of the new treatment.

¹ Hay A, Cheung M. CAR T-cells: costs, comparisons, and commentary. *J Med Econ*. 2019; 22(7): 613-615, DOI: 10.1080/13696998.2019.1582059

² Berdeja, J. et. al. Update of CARTITUDE-1: A phase 1b/2 study of JNJ-4528, a B-cell maturation antigen (BCMA)-directed CAR-T cell therapy, in relapsed/refractory multiple myeloma. Abstract #8505 [Oral]. To be presented at American Society of Clinical Oncology Virtual Scientific Program 2020.

³ Cho SF, Anderson KC, Tai YT. Targeting B-cell maturation antigen (BCMA) in multiple myeloma: potential uses of BCMA-based immunotherapy. *Front Immunol*. 2018;9:18-21.

⁴ Myeloma in Australia statistics, Cancer Australia [Link](#) accessed October 2020

Specifically, IHPA and the National Health Funding Body have a process for funding of chimeric antigen receptor (CAR-T cell) therapy under similar arrangements, and IHPA has indicated that this method could be utilised for other new highly specialised therapies.

In relation to the above context of high cost, highly specialised therapies, and specifically CAR-T therapies, Johnson and Johnson have an interest in bringing new CAR-T therapies to market, however there is no publicly available information on processes that are important for us to understand such as:

- How new CAR-T therapies and the introduction of possibly new diagnosis or procedure codes in the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD10-AM) classification system, will allow identification of new technologies in the activity and cost data be provided to IHPA?
- To what extent would new CAR-T therapies or new indications utilise the same method?
- What specific ABF mechanisms are being considered for CAR-T funding?
- What is the timeframe of moving funding of CAR-T from retrospective reconciled funding to funding within the ABF framework?
- Can the referenced 'Attachment A' be made public? *"The clinical pathway prepared by Peter MacCallum Cancer Centre (Attachment A) is based on clinical trials and patients currently registered"*

Johnson and Johnson request that consideration be given to publication of the process.

Consultation Paper on the Pricing Framework for Australian Public Hospital Services 2021-22 provides a list of Consultations Questions, which are summarised in Appendix 1 (page 48) and we are able to respond to the following:

Are the Pricing Guidelines still relevant in providing guidance on IHPA's role in pricing Australian public hospital services? (Page 11)

- We believe the Pricing Guidelines are still relevant and can be further clarified by including direction on how new CAR-T treatment will be incorporated that have different indications, to the current CAR-T therapies investigated by IHPA

Is there support to replace the hard copies of the AR-DRG Definitions Manual and ICD-10-AM/ACHI/ACS with electronic versions? (page 18)

- We would support the replacement of hard copies of the AR-DRG Definitions Manual and ICD-10-AM/ACHI/ACS with electronic versions

Do you support the adjustment IHPA has proposed for NEP21? (Page 21)

- We would support the adjustment IHPA has proposed for NEP21

What comments do stakeholders have regarding the innovative funding models being considered by IHPA? (Page 38)

- We would like to understand if these innovative funding models are being considered for CAR-T therapy?

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens — support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.