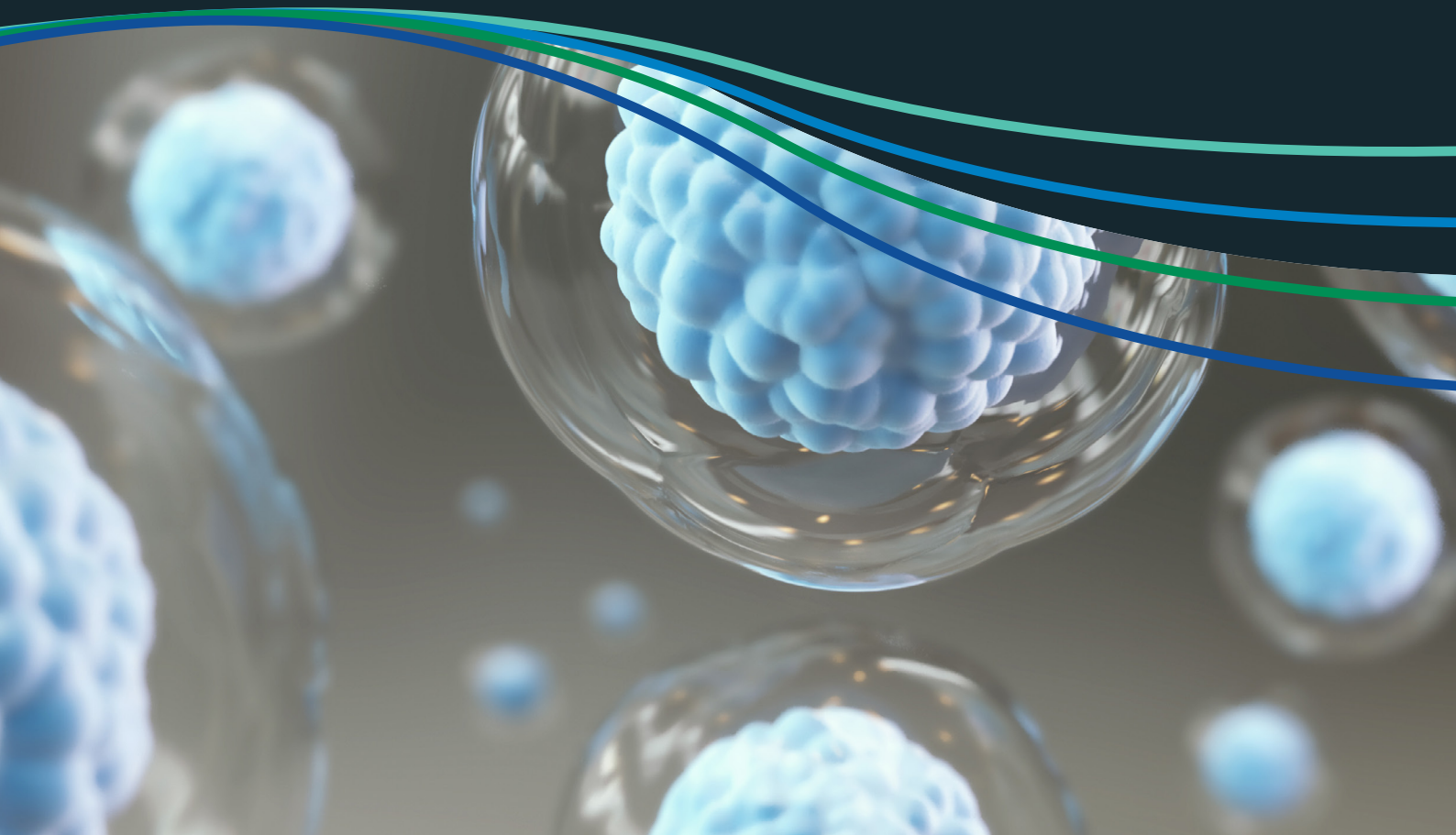




# Guidelines for the reporting and funding of high cost, highly specialised therapies under the National Health Reform Agreement

July 2025



## **Guidelines for the reporting and funding of high cost, highly specialised therapies under the National Health Reform Agreement Version 1.0 July 2025**

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# Provisions under the addendum

The Addendum to the National Health Reform Agreement (NHRA) 2020–26 outlines specific arrangements for the funding of new high cost, highly specialised therapies (HSTs).

HSTs are Therapeutic Goods Administration (TGA) approved medicines and biologicals delivered in public hospitals where:

- ▶ the therapy and its conditions of use are recommended by the Medical Services Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC)
- ▶ the average annual treatment cost at the commencement of funding exceeds \$200,000 per patient (including ancillary services) as determined by the MSAC or PBAC with input from the Independent Health and Aged Care Pricing Authority (IHACPA)
- ▶ the therapy is not otherwise funded through a Commonwealth program, or the costs of the therapy are not appropriately funded through a component of an existing pricing classification.

The arrangements under the NHRA are:

- ▶ the Commonwealth, for these types of therapies, will provide a contribution of 50% of the growth in the efficient price or cost (including ancillary services), instead of 45%; and
- ▶ they will be exempt from the funding cap at clause A56 of the addendum for a period of two years from the commencement of service delivery of the new treatment.
- ▶ Upon commencement of service delivery of the new treatment in a state or territory, the state or territory may request advice from the Administrator of the National Health Funding Pool (the Administrator) on the operation of the cap exemption for that treatment in that state or territory.

## Inclusion of new HSTs in NHRA funding arrangements

Health technology assessment (HTA) is the systematic evaluation of the properties and effects of a health technology. It considers direct and intended effects, as well as its indirect and unintended consequences, with the main purpose of supporting informed decision making. Health technologies include tests, devices, medicines, vaccines, procedures, programs and systems.

The addendum stipulates that decisions on referring applications for new HSTs, which are likely to be delivered in public hospitals, for HTA will be made jointly by the Chairs of MSAC and PBAC, along with a nominated health minister representative.

IHACPA provides input to MSAC or PBAC as required but does not have a role in the HTA process for HSTs. Rather, IHACPA receives advice from the Commonwealth when conditions of public subsidy have been agreed for a HST. IHACPA then includes it in the annual national efficient cost (NEC) determination and the Pricing Framework for Australian Public Hospital Services. The funding and reconciliation process for a HST recommended for delivery in public hospitals is discussed in further detail below in 'Reporting requirements'.

# Eligibility criteria

In line with the provisions under the addendum, IHACPA's remit is to establish eligibility, scope and reporting criteria for HSTs in-scope for Commonwealth funding under the NHRA.

IHACPA has determined the following prerequisites for HSTs considered in-scope for Commonwealth funding under the HST clauses of the addendum:

- ▶ MSAC and Commonwealth recommend the delivery of the HST, in line with the approved indications.
- ▶ States and territories confirm the treatment centre/s delivering the HST.
- ▶ States and territories demonstrate the patient specifications meet the approved indications for the HST.
- ▶ States and territories commit to reporting activity and cost data through activity based funding (ABF) data submissions and the National Hospital Cost Data Collection (NHCDC).

## Scope of the Commonwealth funding cap exemption

### In-scope activity

After a HST has been recommended for use in public hospital services, a Deed of Agreement is signed between the supplier and the Commonwealth and the 2-year funding cap exemption period begins from commencement of service delivery.

To be considered in-scope for the Commonwealth funding cap exemption under the specific arrangements outlined in Schedule C of the addendum, the treatment centre must be accredited to provide the HST. In-scope activity for the exemption includes:



- ▶ Activity related to the establishment and ongoing accreditation of the treatment centre, including activity related to the delivery of a new HST at an existing treatment centre.
- ▶ Services related to the approved indications for the delivery of a HST to registered patients, where costs are incurred by the treatment centre.

Activity that is in-scope for the Commonwealth funding cap exemption may include patient referral processes and associated tests and diagnostic procedures, consultations, treatments, monitoring and community-based or other non-admitted care. Accommodation and transport of the patient, and carer if required, where those costs are incurred by the treatment centre, are also considered in-scope for the Commonwealth funding cap exemption.

### **Out-of-scope activity**

Activity that is out-of-scope for the Commonwealth funding cap exemption under the specific arrangements outlined in Schedule C of the addendum is defined as:



- ▶ Services provided to patients by treatment centres not accredited to provide the HST.
- ▶ Services provided to patients in contraindication of the approved indications for the HST.
- ▶ Services provided to patients after a treatment centre has been registered for service delivery for more than 2 years, as per the funding cap exemption.

As outlined in the addendum, HSTs recommended for delivery in a public hospital setting by MSAC will be exempt from the Commonwealth funding cap for a period of 2 years from the commencement of service delivery of the new treatment.

After a treatment centre has been delivering the service for more than 2 years, services provided are no longer eligible for the funding cap exemption. However, they remain in-scope for NHRA funding.

If new HST service delivery begins at a treatment centre that has been registered for more than 2 years, the state or territory may request advice from the Administrator on whether the funding cap exemption applies to that treatment.

IHACPA also notes that any HST activity that is out-of-scope for block funding under the HST clauses in the addendum will be funded through the ABF pool and priced under the national pricing model.

# Reporting requirements

To enable funding reconciliation, states and territories are required to submit activity and cost data, including:

- ▶ the treatment centre/s and local hospital networks (LHNs) providing the HST
- ▶ the dates on which HST services were provided
- ▶ the volume of patients receiving the HST
- ▶ the costs incurred, including the breakdown of fixed and variable costs for the HST.

## Activity data submissions

Activity data for HST patients will be included in the ABF data files as part of the quarterly ABF submissions. This includes reporting of the 'Funding Source / Program Indicator' data item as part of the ABF data request specifications for 'Alternative Funding Source'.

## Cost data submissions

States and territories must provide cost data for HST patients to the Administrator within 3 months of the completion of the relevant financial year. These data must also be reported in the NHCDC.

Fixed costs are defined as those associated with establishing and accrediting the treatment centre, including minimum staffing requirements. Variable costs are defined as those directly or indirectly attributable to a registered patient over the course of their treatment.

## Funding and reconciliation

States and territories eligible for HST funding arrangements under the NHRA must provide IHACPA with the estimated cost of each HST (including ancillary services) and the anticipated volume of patients as part of the development of the annual NEC determination. Updated cost estimates will be published as part of the Supplementary Block Funding Advice to the Administrator of the National Health Funding Pool. Unlike other block funded services and hospitals, the funding for HSTs will be reconciled against actual cost data submitted to the Administrator.

The Administrator will use activity and cost data identified through the ABF activity data submissions and the NHCDC to determine the actual HST costs for each state and territory. These costs will be excluded from the Commonwealth funding calculation for ABF services.

HSTs under the Schedule C arrangements in the addendum remain in-scope for NHRA funding after the conclusion of the Commonwealth funding cap exemption period. This includes the HST product, fixed costs associated with operating a treatment centre and all patient activity while registered on the HST program.



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