MSAC Application 1791

Dinutuximab beta for primary relapse and refractory high-risk neuroblastoma

Application or referral for other medical service or health technology

MSAC Application ID:
MSAC 1791
Application title:
Dinutuximab beta for primary relapse and refractory high-risk neuroblastoma.
Submitting organisation:
RECORDATI RARE DISEASES AUSTRALIA PTY. LTD.
Submitting organisation ABN:
26627263094

Application description

Succinct description of the medical condition/s:
The medical condition is high risk neuroblastoma in patients who experience primary (first) relapse or are refractory to treatment. Relapse can occur at any stage of treatment (induction, consolidation, maintenance and post-maintenance). The risk classification scheme presented by the International Neuroblastoma Risk Group (INRGSS) is the Modified International Neuroblastoma Risk Groups (mINRG). Children diagnosed with NBL are classified based on their INRG stage, age, and tumour biology as high, intermediate, low and very low-risk.
Succinct description of the service or health technology:
Dinutuximab beta (monoclonal antibody therapy) used in conjunction with combination chemotherapy.

Application contact details

Are you applying on behalf of an organisation, or as an individual?
Organisation
Is the applicant organisation the organisation you are representing in the HPP today?
Yes
Applicant organisation name:
RECORDATI RARE DISEASES AUSTRALIA PTY. LTD.

Application details

Please select the program through which the health technology would be funded:
National Health Reform Agreement Addendum (Highly specialised therapies)
Please provide justification for selecting the above program:
The current funding for dinutuximab beta (Qarziba) is via the NHRA Addendum (HST) program for high risk neuroblastoma and the purpose of this application is to expand funding to those high risk neuroblastoma patients who have experienced a primary relapse or are refractory to treatment.
Is the application for a new listing or a change to an existing listing?
Change to existing listing

Provide a rationale for the change to an existing listing:
The current funding for Qarziba is via the NHRA Addendum (HST) program for high risk neuroblastoma and the purpose of this application is to expand funding to those high risk neuroblastoma patients who have experienced a primary relapse or are refractory to treatment.
It follows that this application is a change to the existing funding criteria.
What is the type of service or health technology?
Therapeutic

PICO set

Application PICO set 1: Primary Relapsed and Refractory High Risk Neuroblastoma

Population

Describe the population in which the proposed health technology is intended to be used:
Patients with high-risk neuroblastoma (HRNBL) who are refractory during induction or have had a primary (first) relapse during or after one of the 3 treatment stages: induction, consolidation or post-consolidation/maintenance.
Select the most applicable Medical condition terminology (SNOMED CT):
High Risk Neuroblastoma

Intervention

Name of the proposed health technology:
Qarziba (dinutuximab beta) together with combination chemotherapy.

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This include identifying health care resources that are needed to be delivered at the same time as the comparator service:
The combination chemotherapy nominated by Australian clinicians in a survey was topotecan/irinotecan + temozolomide.

Outcomes

Outcome description - please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Major health outcomes:
- Overall response rates (ORR): complete response (CR) and partial response (PR)
- Progression free survival (PFF) or Event Free Survival (EFS)
- Overall Survival (OS)

Health Harms: Reporting of adverse events.
This is not a test. The changes to the treatment algorithm are presented elsewhere.

Specified restrictions for funding

Please add one or more items, with specified restriction for funding, for each Population / Intervention:
Proposed item: AAAAA
Is the proposed item restricted:
Yes - restricted
Provide a short description of the restriction:
Patients with HRNBL who have had a primary relapse or who are refractory.
Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:
Clinical Criteria:
Patients with high risk neuroblastoma that have relapsed for the first time or are refractory to treatment.
Proposed price of supply:
REDACTED
Indicate the overall cost per patient of providing the proposed health technology:
REDACTED
Provide details and explain:
The amount of dinutuximab required for each patient depends on the patient's size and the number of courses required to elicit a response. The dosing schedule for chemoimmunotherapy involves administering dinutuximab in conjunction with combination chemotherapy as a 7-day continuous infusion (10 mg/m2/24hr), given in a 28-day cycle (with the cycle length determined by the relevant chemotherapy protocol). Typically, patients use between REDACTED vials but there can be significant inter-patient variability.
How is the technology / service funded at present? (For example: research funding; State-based funding; self funded by patients; no funding or payment):
Dinutuximab beta is currently funded under the NHRA Agreement Addendum 2022-25, under the HST program for those patients who have achieved a response to treatment.
Use of dinutuximab in the refractory and relapsed setting in combination with combination chemotherapy is not currently funded with the associated costs borne by individual treating hospitals.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?
Superior
Please state what the overall claim is, and provide a rationale:
Dinutuximab in combination with chemotherapy provides greater overall survival (OS) and improve progression free survival (PFS) compared to chemotherapy alone in primary relapsed/refractory patients.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
REDACTED patients over 2 years based on a survey of paediatric oncologists.
Provide the percentage uptake of the proposed health technology by the proposed population:
Year 1 estimated uptake (%):
REDACTED
Year 2 estimated uptake (%):
REDACTED
Year 3 estimated uptake (%):
REDACTED
Year 4 estimated uptake (%):
REDACTED
Estimate the number of patients who will utilise the proposed technology for the first full year:
REDACTED
Optionally, provide details:
Based on the REDACTED patients expected to relapse or are refractory (derived from the survey) over 2 years, it follows that an uptake rate of REDACTED% in the first year results in REDACTED RRHRNBL patients using Qarziba (in combination with chemotherapy). It is unlikely that all eligible RRHRNBL patients will use Qarziba given that there are clinical trials also available.
Will the technology be needed more than once per patient?
Yes, multiple times
Over what duration will the health technology or service be provided for a patient? (preferably a number of years):
Typically 6 treatment cycles (28 days each).
Optionally, provide details:
The length of a treatment cycle is determined by the length of the chemotherapy cycle.
What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):
Typically 6 treatment cycles (28 days each).
Optionally, provide details:

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:
Professional body name:
Australian and New Zealand Children's Haematology and Oncology Group (ANZCHOG)

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:
Professional body name:
RECORDATI RARE DISEASES AUSTRALIA PTY. LTD.

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:
Number of organisations listed: 2
Professional body name:
NEUROBLASTOMA AUSTRALIA

Number of organisations listed: 2
Professional body name:
RARE CANCERS AUSTRALIA LTD

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:
Professional body name:
Paediatric oncologists.

Professional body name:
Paediatric oncology nurses

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
Yes
Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?
Yes
Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?
No

Please enter all relevant ARTG ID's:	
ARTG ID	**ARTG name**
321016	QARZIBA dinutuximab beta 4.5 mg/mL concentrate for solution for infusion, 20 mg/4.5 mL vial

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?
No
Provide details:
Qarziba is indicated for the treatment of high-risk neuroblastoma in patients who have previously received induction chemotherapy and achieved at least a partial response. This covers patients that are relapsed, but not those who are refractory. REDACTED