Genetic testing for neurotrophic receptor tyrosine kinase fusion in patients with locally advanced or metastatic solid tumours

Last updated: 23 June 2022

- From 1 July 2022, patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma will be able to access Medicare Benefits Schedule (MBS) funded genetic testing for neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion status, to determine eligibility for access to a tropomyosin receptor kinase (Trk) inhibitor under the Pharmaceutical Benefits Schedule (PBS).

What are the changes?

From 1 July 2022, four new genetic testing items will be introduced to the MBS to determine eligibility for access to a PBS-funded Trk inhibitor in patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma:

- new MBS items 73430, 73431 and 73432 will fund fluorescence in-situ hybridisation (FISH) tests of tumour tissue for the evaluation of *NTRK* gene fusion status in patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma. Item 73430 covers a single FISH test, item 73431 covers two tests and item 73432 covers 3 or more tests; and
- new MBS item 73433 will fund next generation sequencing (NGS) testing of tumour tissue for the evaluation of *NTRK* gene fusion status in patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma.

Items 73430, 73431, 73432 and 73433 must be requested by a specialist or consultant physician to determine if requirements relating to *NTRK* gene fusion status for access to a Trk inhibitor under the PBS are fulfilled.

Only one item, either 73430, 73431, 73432 or 73433, can be claimed per patient per cancer diagnosis.

For private health insurance purposes, items 73430, 73431, 73432 and 73433 will be listed under the following clinical category and procedure type:

- Clinical category: Support list (pathology)
- Procedure type: Type C

Why are the changes being made?

In November 2021, the Medical Services Advisory Committee (MSAC) supported an application to create four new MBS items for *NTRK* fusion testing to determine eligibility for treatment with the Trk inhibitor larotrectinib in patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin, and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma. In March 2022, the Pharmaceutical Advisory Committee (PBAC) recommended the PBS listing of larotrectinib for this patient population.

How will these changes affect patients?

The listing of these new items will mean that patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma will have access to MBS funded testing for *NTRK* gene fusion status, to determine eligibility for access to treatment with a PBS listed Trk inhibitor (including larotrectinib).

What does this mean for providers/referrers/other stakeholders?

From 1 July 2022, specialists and consultant physicians will be able to request MBS funded testing to detect *NTRK* gene fusion in tumour tissue from patients less than 18 years of age with locally advanced or metastatic solid tumours of any origin and adult patients with locally advanced or metastatic mammary analogue secretory carcinoma of the salivary gland or locally advanced or metastatic secretory breast carcinoma.

Who was consulted on the changes?

Consultation has been undertaken with key stakeholders, clinical experts and providers, and consumer health representatives as part of the MSAC process.

Consultation was also undertaken with the Royal College of Pathologists of Australasia.

How will the changes be monitored and reviewed?

Pathology services items will be subject to MBS compliance processes and activities, including random and targeted audits which may require a provider to submit evidence about the services claimed.

Significant variation from forecasted expenditure may warrant review and amendment of fees, and incorrect use of MBS items can result in penalties including the health professional being asked to repay monies that have been incorrectly received.

MBS pathology items will be reviewed by MSAC approximately 24 months post-implementation.

Where can I find more information?

If you have a query relating to the interpretation of the MBS, you should email AskMBS. Subscribe to 'News for Health Professionals' on the Services Australia website to receive regular news highlights.

If you are seeking advice in relation to Medicare billing, claiming, payments, or provider numbers, please visit the Health Professionals page on the Services Australia website or contact their Provider Enquiry Line – 13 21 50.

This sheet is current as of the Last updated date shown above, and does not account for MBS changes since that date.