AUSTRALASIAN ASSOCIATION of
Nuclear Medicine
Specialists (AANMS)

UPDATE:
Technetium-99 shortage:
Radiopharmaceuticals Substitution Available from Tuesday 17 September 2019

Dear Member

The AANMS received welcome news early this morning that on Saturday 14 September, six temporary items were added to the Medicare Benefits Schedule (MBS) to allow patients to have continued access to common nuclear medicine diagnostic imaging services during the shortage in supply of Technetium-99m (Tc-99m).

As indicated in my previous email, expanding access to these additional services will assist in making more technetium-99 available to those facilities without PET cameras, which will be especially helpful to the smaller practices and those in rural and regional areas.

The items will be eligible for patient rebates from Tuesday 17 September 2019 and will be available for an initial period of three months.

These parallel items use PET and/or alternative radiopharmaceuticals to provide equivalent diagnostic imaging services. The items have the same request arrangements (i.e. can be requested by any medical practitioner, including GPs) and schedule fee as the items on which they were modelled.

The Department has prioritised in this substitution plan the most common nuclear medicine diagnostic imaging services affected by the shortage. The AANMS will continue its discussions with the Department in relation to substitution for other nuclear medicine services, notably for infection and renal imaging, and it is hoped they will also be added to the substitution arrangements in the near future.

The items are set out in the Health Insurance (Section 3C Diagnostic Imaging - Nuclear Medicine Services) Determination 2019, which includes the new item descriptors and which can be found at:
https://www.legislation.gov.au/Details/F2019L01195
(please copy and paste this link into your browser).

Four unapproved radiopharmaceuticals are required for use with the temporary MBS items. As these products are not included in the Australian Register of Therapeutic Goods, they are known as 'unapproved' goods and are required to be accessed through one the following access pathways:

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- Special Access Scheme (https://www.tga.gov.au/form/special-access-scheme)
- Authorised Prescriber scheme (https://www.tga.gov.au/form/authorised-prescribers)

In order to assist access to these radiopharmaceuticals, the TGA has added the following four unapproved radiopharmaceuticals to the Special Access Scheme Category C Medicines List (known as the Therapeutic Goods (Authorised Supply of Medicines) Rules 2019):

Item	Active ingredient	Dosage form	Route of administration	Indication
25	F18 Myocardial Perfusion Tracer (18F flurpiridaz)	Injection	Intravenous	myocardial perfusion study
26	F-18 NaF (Sodium fluoride)	Injection	Intravenous	bone study
30	Gallium- 68 (Ga-68) Galligas	Aerosol	Inhalation	lung ventilation study
31	Gallium-68 (Ga-68) - MAA	Injection	Intravenous	lung perfusion study

(Please note that GMS has Australian distribution rights for 18F flurpiridaz, but is unable to say at this time when it will be available for distribution.)

SAS Category C is a notification pathway which allows health practitioners to supply specified unapproved therapeutic goods that are deemed to have an established history of use without first seeking prior approval.

The preferred route for submitting notifications is through the SAS Online System (https://www.tga.gov.au/special-access-scheme-and-authorised-prescriber-online-system).

Notifications may be submitted by the prescribing health practitioner or by a health practitioner on behalf of a prescribing medical practitioner within 28 days after the supply.

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President