From 1 September 2015, the way PBS subsidised growth hormone is prescribed, dispensed and accessed will align with other PBS subsidised medicines. The new arrangements will be more flexible for patients and prescribers, with a stronger role for community pharmacies.

The new arrangements will contribute to PBS sustainability. Like other PBS subsidised medicines, patients will contribute a PBS patient co-payment for each supply. Patient and prescriber eligibility criteria will remain unchanged.

**Overview of the changes**
While prescriber eligibility requirements remain unchanged, from 1 September 2015 specialist paediatric endocrinologists and paediatricians will use a revised process to treat patients with growth hormone under the PBS.

Currently, prescribers make a written application to the Department of Health to prescribe growth hormone for patients under a number of categories. These applications are assessed by the Department of Health against the *Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Programme*. Some applications are referred to the Growth Hormone Advisory Committee (GHAC) for advice. Prescribers make additional applications for approval to continue therapy.

From 1 September 2015, prescribers will make written application to the Department of Human Services (DHS). A series of questions will guide prescribers, in a similar way to the current application process, with patient dose levels managed by prescribers rather than by existing incremental dosing levels. DHS will process applications in order of receipt.

Separate PBS restriction criteria for all treatment phases have been developed from the *Guidelines*, in consultation with the GHAC and the Pharmaceutical Benefits Advisory Committee (PBAC).

Approved PBS Authority prescriptions will be used by a patient’s parents/guardians to obtain growth hormone supplies at the pharmacy of their choice. The Department of Health will no longer manage the ordering and monitoring of growth hormone supplies for individuals.

In summary, from 1 September 2015, the process by which prescribers receive approval to prescribe growth hormone will align with other authority-required PBS subsidised medicines.
PRESCRIBER AND CLINIC FREQUENTLY ASKED QUESTIONS

How will my patients be transitioned to the new system?
The Department of Health will be accepting complete applications up to 31 August 2015 (inclusive). These applications will be processed under the current arrangements, and supplies will be ordered in early September 2015 by the Department of Health. Please ensure the patient has collected all supplies from their nominated pharmacy before submitting an application for continued supply via the new arrangements.

Since 6 July 2015, to assist with the transition to the new arrangements, the Department of Health has been ordering the full six months’ supply of growth hormone for patients for whom an initial, reapplication or recommencement supply has been ordered and has been requesting six months’ worth of consumables from the supplier. Automatic resupplies (balance supplies) have also been ordered ahead of schedule, to assist with the transition. Patients’ parents/guardians should collect these supplies as soon as possible.

PBS subsidised growth hormone supplies ordered by the Department of Health, under the current arrangements, do not attract a patient PBS co-payment.

All applications for PBS subsidised growth hormone on and from 1 September 2015 MUST be via the new arrangements, which are outlined below.

| Patient attends appointments with the prescriber, to enable the collection of all required data |
| Prescriber completes application and submits application to the Department of Human Services |
| Department of Human Services assesses the application and notifies the prescriber of the outcome |
| Prescriber provides the patient with the authorised prescription and liaises with the pharmaceutical company to organise consumables (pen needles/syringes etc) |
| Patient presents authorised prescription to any PBS-approved pharmacy |
| PBS-approved pharmacy orders supplies |
| PBS-approved pharmacy notifies the patient when the supplies have arrived |
| Patient pays a co-payment (one co-payment applies to each 3 month supply) and collects supplies. Patient collects consumables. |
| PBS-approved pharmacy submits reimbursement claim to the Department of Human Services |

Cycle begins again
What will the new application forms look like?
From 1 September 2015, PBS growth hormone application forms will be in a fillable PDF format, available for download from the DHS website (www.humanservices.gov.au).

There will be 5 types of application forms published:
1. Initial treatment
2. Continuing treatment
3. Continuing treatment as a reclassified patient (where a patient is continuing treatment but under a different category)
4. Recommencement of treatment (where a patient has had a break in treatment and needs to start growth hormone treatment again under the same category)
5. Recommencement of treatment as a reclassified patient (where a patient has had a break in growth hormone treatment and needs to start treatment again under a different category)

How do I apply?
You will need to send:
- a completed Authority Application Supporting Information Form (with any required supporting information) relevant to the growth hormone application category and treatment phase; and
- a completed PBS Authority prescription, to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

What will the application processing time be under the new arrangements?
DHS will generally process applications in order of receipt and they will be completed as soon as possible. As an estimate, please allow at least two weeks for DHS to process the application once it has been received. Prescribers will also need to factor in the time required for the application to be received by DHS via the post and the time it will take for the approved authority prescription to be returned to the prescriber or patient’s parent/guardian. Prescribers also need to be aware that once the patient’s parent/guardian presents the approved authority prescription to the pharmacy, time will be required for the pharmacy to order the growth hormone supply and for it to be delivered to that pharmacy.

To ensure continuity of treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to DHS at least two weeks prior to the patient completing their current treatment course.

What do I need to do if I have an urgent application for submission to DHS?
If you have a genuinely urgent application you can post it to DHS using an ‘Express Post’ envelope marked as ‘Urgent’ as well as marking the application ‘Urgent’. DHS also recommend that prescribers call 1800 700 270 (hours of operation: 8am to 5pm EST, Monday to Friday) to advise that an urgent application is being submitted.
How will I be notified of the outcome of the application?
If the application is approved, DHS will send the approved PBS Authority form to either the patient’s parent/guardian, or the prescriber, in accordance with the prescriber’s instruction on the PBS Authority prescription. If the approved prescription is sent to the patient’s parent/guardian, DHS will also advise the prescriber separately. If the application is not approved, DHS will advise the prescriber in writing.

Will repeat prescriptions be permitted?
Yes. Prescribers should complete the application form and prescription seeking authority to treat their patients for the following periods at the dose prescribed and specifying the brand name of the product of their choice:

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>Initial and recommencing treatment</td>
<td>16 weeks’ supply + 1 repeat (32 weeks total)</td>
</tr>
<tr>
<td>Continuing treatment</td>
<td>13 weeks’ supply + 1 repeat (26 weeks total)</td>
</tr>
</tbody>
</table>

Will the Growth Hormone Program remain a Section 100 Program?
Yes. PBS-subsidised growth hormone will still be provided as a special arrangement under Section 100 of the National Health Act 1953.

Can prescriptions be written for brand-specific growth hormone medicines?
Yes. The prescriber MUST specify in the application form and on the authority prescription the brand of growth hormone (including the form and strength) that is to be prescribed for the patient. Note that the same brand (including the form and strength) must be dispensed for both the original and the repeat supplies. If the brand needs to be changed during the treatment period, this will require a separate authority approval from DHS.

Who is responsible for calculating patient doses under the new arrangements?
The prescriber will be responsible for calculating each patient’s weekly dose and the number of cartridges/boxes required for the treatment period. A spreadsheet is attached to assist prescribers and clinic staff in determining a dose and the number of cartridges/boxes subsequently required for the treatment period.

The requirement to seek approval for incremental dose increases will no longer apply, although existing maximum doses applicable to the approved treatment category will continue.

Will there be a change to the data requirements?
The data required for an application will remain largely unchanged, except for applications for continuing or recommencement treatment periods (with or without reclassification) where growth data (height and weight) from both the start and end of the most recent 6 month treatment period will need to be submitted.

Do I need to send supporting evidence with the application?
Yes, if the application form requires it. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the
prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for two years after the date of the prescription, to which the records relate, is written.

**What needs to be done if growth hormone supplies are compromised?**
If a patient’s growth hormone supply is compromised, either at home or at the pharmacy, prescribers will need to contact DHS for information about obtaining a new approval.

**Will patients be allocated an individual number (eg an H number) to track supplies?**
No. PBS subsidised growth hormone will be ordered and dispensed by pharmacies on an individual basis upon presentation of a PBS authority prescription. Accordingly, the current H-number tracking of supplies will cease as supplies under the old arrangements are exhausted.

**Who is responsible for ordering consumables?**
As growth hormone consumables are not PBS items, the Department of Health cannot mandate arrangements for ordering and supply. Clinics/prescribers should liaise with the relevant pharmaceutical company to discuss arrangements for patients to obtain consumables.

**What is not changing for prescribers?**
The most recent data provided in applications will still need to be no older than three months, and the most recent bone age reading provided will still need to be no older than twelve months.

Clinics/prescribers will still need to check with the patient’s parent/guardian as to how much stock is held at home, as potential non-compliance needs to be taken into account when applying for further treatment.

If a patient is approved for initial treatment or recommencement treatment, further treatment (beyond the initial 32 weeks) will still be subject to assessment of response, and the patient will still be required to meet the clinical criteria for continuing treatment (for the approved treatment category).

**Who do I contact if I have any questions regarding the new arrangements?**
Prior to 1 September 2015, enquiries should be directed to the Department of Health at HGH@health.gov.au

From 1 September 2015 onwards any queries concerning the arrangements to prescribe PBS subsidised growth hormone need to be directed to the DHS on 1800 700 270 (hours of operation: 8am to 5pm EST, Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) will be available on the DHS website at www.humanservices.gov.au
PHARMACIST FREQUENTLY ASKED QUESTIONS

What is changing for pharmacists?
From 1 September 2015, pharmacies will start to see growth hormone PBS Authority prescriptions being presented for dispensing. These forms can originate from private specialists, or private and public hospital clinics. These prescriptions may be dispensed by community pharmacies, private hospital pharmacies and public hospital pharmacies, whether they originate from a public or private hospital clinic or a private specialist. Note that prescriptions written for public patients of NSW and ACT public hospital clinics cannot be dispensed under the PBS, as these jurisdictions do not participate in the Pharmaceutical Reforms.

Pharmacists will need to ensure that the Authority prescription presented for dispensing has been approved by DHS, as indicated by a red approval stamp on the PBS Authority prescription. DHS will also endorse the prescription with the quantity to be dispensed, the number of Repeats allowed (if any), and the PBS Item Code for pharmacists to use in dispensing and claiming (with no brand substitution permitted).

Hospital authorities and community pharmacists will be remunerated for dispensing growth hormone, at the rate applying on the date of supply, for valid PBS prescriptions dated 1 September 2015 or later. PBS patient co-payments apply for prescriptions dated 1 September 2015 or later, with usual co-payment amounts applying. Dispensing software will be updated to feature these changes.

What about supplying subsidised growth hormone before 1 September 2015?
Existing growth hormone supply arrangements will remain in place until 31 August 2015 (inclusive), and may continue for some patients beyond 1 September, depending on the patient’s stage in therapy. Existing arrangements involve the ordering of growth hormone supplies by the Department of Health for delivery by growth hormone manufacturers direct to pharmacies, at no cost to the pharmacy. No PBS patient co-payments apply to these supplies. It is expected that these arrangements will be exhausted before the end of 2015.

What happens to private (non-PBS) growth hormone prescriptions from 1 September 2015?
The new arrangements do not affect dispensing of private growth hormone prescriptions.

How will pharmacies obtain growth hormone stock?
PBS growth hormone will be available to pharmacies in the same way as any other PBS medicine. Pharmacists will be responsible for ordering PBS subsidised growth hormone supplies on presentation of a valid PBS Authority prescription.

From 1 September 2015 what happens to excess stock held by pharmacies?
Excess stock held by pharmacies (not stock already allocated to a patient and awaiting collection) as at 1 September 2015 may not need to be returned to the supplier or be destroyed. It may be retained for dispensing to eligible growth hormone patients, in consultation with the Department of Health and suppliers, to ascertain suitability.
PATIENT FREQUENTLY ASKED QUESTIONS

What is changing for patients?
From 1 September 2015, patients will have greater choice about where they access PBS subsidised growth hormone, through either a community, private or public hospital pharmacy.

To better align with other PBS medicines, patients will pay a co-payment for each dispensing of growth hormone. Patient co-payments for 2015 are $6.10 for concessional patients and $37.70 for non-concessional patients. Standard patient eligibility criteria and entitlement rules will also apply, enabling patients to use the Safety Net and patient refund arrangements.

Parents/guardians need to be aware that the pharmacist will have to order the growth hormone supply in when they are given an approved PBS authority prescription, and that this may take some days to arrive. Please keep this in mind to ensure the patient does not run out of supplies before a new supply is available.

As growth hormone consumables are not PBS items the Department of Health cannot make arrangements for patients to get consumables such as syringes, pen needles and sharps containers. Clinic nurses and/or doctors will need to advise parents/guardians of what arrangements have been put in place for supply of growth hormone consumables.

What is the PBS Safety Net?
The PBS Safety Net provides further assistance to those Australians and Australian families who require a large number of PBS prescriptions over a calendar year.

After reaching the Safety Net threshold, general patients pay for further PBS prescriptions at the concessional co-payment rate and concession card holders are dispensed PBS prescriptions at no further charge for the remainder of that calendar year.

In order to access the Safety Net arrangements, patients need to maintain records of their PBS expenditure on a Prescription Record Form. These forms are available from all pharmacies. A Safety Net Entitlement card or Safety Net Concession Card can be issued by the pharmacist once the threshold is reached.

Will I have to pay the patient co-payment for a supply of growth hormone ordered by the Department of Health prior to 1 September 2015?
No. Patient co-payments only apply to supplies of growth hormone made from a valid PBS Authority prescription dated 1 September 2015 or later and ordered by the pharmacy.

What’s not changing for patients?
Under the new arrangements, patient eligibility requirements will remain the same.

Patients will continue to visit their specialist medical practitioner for assessment and to obtain a prescription for growth hormone.