



Named Patient Pharmaceutical Assessment (NPPA)

Questions and Answers for clinicians

The Named Patient Pharmaceutical Assessment (NPPA) Policy sets out PHARMAC's process for considering applications for individual patients who are seeking funding for treatments not listed (either, at all, or for the named patient's clinical circumstances) on the Pharmaceutical Schedule.

1. What is the purpose of the NPPA Policy?

The NPPA Policy complements the Pharmaceutical Schedule, in which PHARMAC lists treatments that are subsidised for population groups. Our statutory obligation to provide for exceptional circumstances (situations not sufficiently catered for by the Schedule process used for patient groups) acknowledges there are situations where consideration of an application for funded treatment for an individual, outside of the Schedule decision making process, is warranted.

For PHARMAC to achieve its legislative objective to maintain a Schedule that applies consistently throughout New Zealand, the NPPA Policy must operate in a way that does not undermine the Schedule decision making process.

More information, including the prerequisites and criteria we consider for named patient applications, is described in the NPPA Policy, available online at <http://www.pharmac.govt.nz/nppa>.

2. What situations does the NPPA Policy cover?

There are three main pathways by which your patient can be considered for funding under the NPPA Policy.

Pathway	Purpose
Unusual Clinical Circumstances (UCC)	To provide a process for consideration for funding for named patients whose clinical circumstances are so unusual that PHARMAC is unlikely, for administrative reasons, to consider listing treatments for these circumstances on the Schedule.
Urgent assessment (UA)	To provide a process for PHARMAC to consider funding treatments for named patients where PHARMAC is also considering or is likely to consider the treatment for Schedule listing, but the patient's clinical circumstances justify urgent assessment, prior to a decision on a Schedule listing.
Hospital Pharmaceuticals in the Community (HPC)	To allow District Health Board hospitals to fund a medicine for a patient in the community if this is more affordable for the DHB than paying, via the Schedule funding mechanism, for a different funded treatment that would otherwise need to be provided. PHARMAC's approval is required for any such funding, given DHBs' legislative obligation to act consistently with the Schedule.

More information on each of these pathways, including the prerequisite requirements, can be found online at <http://www.pharmac.govt.nz/nppa>.

If your application does not meet the prerequisite requirements for one pathway we have the discretion to consider whether it could appropriately be assessed under an alternative NPPA pathway.

3. Who can make a NPPA application?

Any authorised prescriber may make a NPPA application under the Unusual Clinical Circumstances (UCC) and Urgent Assessment (UA) pathways.

Only District Health Board clinicians may make NPPA applications under the Hospital Pharmaceuticals in the Community (HPC) pathway. This is because HPC is for DHB hospitals to fund a treatment in the community, where they are otherwise prohibited from doing so as it would undermine the Schedule. For example, a HPC application would need to be made where a patient has been receiving intravenous treatment in the hospital and the DHB clinician wants to change to an orally administered presentation of that treatment which the patient can take in the community and where that oral treatment is not listed in the Schedule.

4. What kinds of things can I apply for under NPPA?

NPPA applications will be considered for treatments that fall within the following categories:

- medicines or medicinal products (intended for self administration or otherwise delivered in a community [non-hospital] setting); and
- hospital cancer treatments not otherwise funded by the hospital (including those administered in hospital).

PHARMAC is in a transition phase with respect to managing non-cancer treatments administered in a hospital setting. While we will generally not consider hospital based treatments under the NPPA Policy, we may consider applications for treatments for chronic conditions which are delivered in-hospital.

5. What are the prerequisites for NPPA?

At a general level, PHARMAC will consider the clinical circumstances of the patient and the associated health-related costs and benefits. We will not consider social circumstances (e.g. dependant children), non-health related costs or benefits arising from treatment (e.g. a return to work) or evidence obtained from a treatment that is already being provided unless that evidence can be applied to the group of patients that individual is in.

Before completing a NPPA application you should consider whether your patient meets the following prerequisites:

A. Tried everything else

The patient has reasonably tried and failed all alternative funded treatments (or alternative treatments have been contraindicated or there are no other treatments available) or has experienced such serious side effects with all other relevant funded treatments that treatment has been ceased or cannot reasonably be continued. This applies to all pathways.

B. Then

EITHER

i. there is a set of Unusual Clinical Circumstances (UCC)

The patient is experiencing an indication or set of clinical circumstances that are so unusual that PHARMAC is unlikely to consider listing treatments for these on the Schedule.

OR

ii. the patient has serious clinical circumstances requiring treatment prior to the time needed for a Schedule assessment or would miss the opportunity for significant clinical improvement in a serious condition (Urgent Assessment – UA)

The patient has serious clinical circumstances and not receiving the treatment within six to 12 months (the general time to complete a Schedule assessment) would lead to either a significant deterioration in a serious clinical condition or the patient would miss the opportunity for significant improvement in clinical outcome (length or quality of life).

OR

iii. the treatment costs less for the DHB than paying for the most likely alternative intervention or outcome (Hospital Pharmaceuticals in the Community – HPC).

- The application is for a DHB hospital to fund a treatment for use in the community for a patient under the care of a DHB hospital clinician (in-patient or out-patient); and
- The treatment is not being used to treat a cancer; and
- The treatment costs less for the DHB than the most likely alternative funded intervention or outcome (be it a medicine or other form of care); and
- The treatment is being sought for a short-term episode of care (around three months) and is not generally for the treatment of a chronic condition.

C. AND has the treatment already been considered by PHARMAC?

If the treatment and indication you are seeking funding approval for has already been considered by PHARMAC and declined for either a Schedule listing or for the same clinical circumstances under NPPA, it is less likely your application will be approved.

If the treatment and indication you are applying for has been considered by PHARMAC for a Schedule listing and is currently prioritised for funding, we will consider your NPPA application while awaiting a Schedule listing for the patient population.

We will soon have an online NPPA Results Tracker for you to see the outcomes of previous NPPA applications (anonymised) to help you determine whether or not to make an application. If you cannot find whether any of the decisions in the Results Tracker may apply to your patient, we can determine this during the assessment process.

6. What about applications for cancer treatments?

Cancer treatments (including those administered in hospital but not otherwise funded in the community) will be considered using the same criteria as are applied to non-cancer treatments administered in the community (i.e. under UCC or UA as appropriate, but not under HPC). Cancer treatments will be considered using the same criteria as are applied to non-cancer treatments funded in the community via UCC or UA. Applying the same set of criteria for the funding of cancer and non cancer treatments will improve equity and national consistency."

7. How do I apply for treatments that meet the HPC prerequisites and cost under \$500?

There is no difference in process. Applications for treatments meeting the prerequisites for the Hospital Pharmaceuticals in the Community pathway and costing under \$500 will need to be made under the HPC pathway as for all other HPC applications.

We hoped to be able to implement a process by which District Health Boards (DHBs) could approve funding, without application to PHARMAC, for all treatments that met the prerequisites for the HPC pathway and cost \$500 or under. Unfortunately, at this stage we're not able to put this in place. We found that because the data requirements to support such a system could not easily be met, implementing such a system would create significant additional work for DHBs and PHARMAC, defeating the purpose of the initiative. We will continue to consider how we can give effect to the flexibility that we'd like to make available, without increasing the resource burden for DHBs.

8. My patient's circumstance meets the prerequisites, what do I do next?

Once you have determined the answers to the questions above and think making an application is appropriate, please complete a NPPA application form. These are available online at <http://www.pharmac.govt.nz/nppa>

9. What if my patient's circumstance does not meet the NPPA Policy prerequisites?

PHARMAC always maintains its discretion to fund treatments for individuals in appropriate circumstances, even if those circumstances do not meet the NPPA Policy prerequisites.

Our usual medicines funding decision making process is the Pharmaceutical Schedule, where subsidised treatments for patient groups are listed. It may be possible for treatments or clinical circumstances that do not qualify for funding under the NPPA Policy to still be considered for Schedule listing or funding for the individual patient.

Contact us if you would like us to consider an application for funding for a treatment that does not meet the NPPA prerequisites. This includes where the treatment is less expensive to the health sector than treatments listed in the Schedule. Where the treatment meets the intent of the relevant Special Authority criteria, but not the technical requirements, please contact us to discuss whether a waiver might be applied.

10. How are NPPA decisions made?

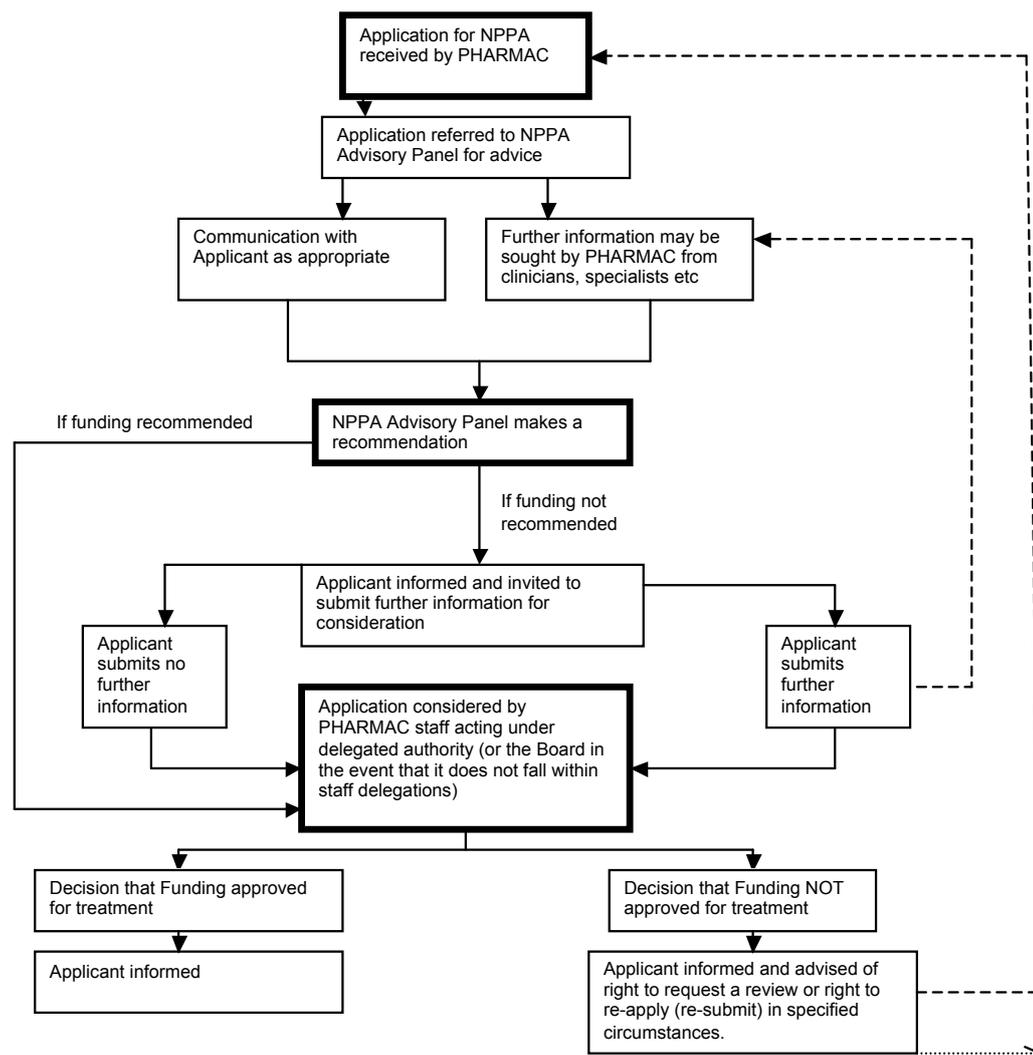
Upon receipt of a NPPA application, PHARMAC staff will initially assess the information provided to determine if the prerequisites are met. For applications that meet the prerequisites we would then undertake more detailed assessment to determine whether, based on the decision criteria, we would fund the treatment. During the process we may present the application and, where necessary, our analysis to the NPPA Advisory Panel for its clinical advice. The NPPA Advisory Panel is a group of expert clinicians that provide advice to PHARMAC on NPPA applications.

If the Advisory Panel recommends that PHARMAC decline your NPPA application, PHARMAC will let you know and provide you with a summary of the Advisory Panel's advice to see if you would like to provide any further information or contest any factual clinical error or clinical judgement that may have been made. If you do provide more information, we will take that into account when deciding on the application, receiving additional clinical input from the Advisory Panel or elsewhere as appropriate.

If the Advisory Panel recommends approval, PHARMAC (either the Board or, more commonly, PHARMAC staff under delegated authority) will consider the Advisory Panel's recommendation alongside our decision criteria and make a decision. If your application is declined and you have new information (e.g. your patient's clinical circumstances change and/or new evidence emerges) you can re-apply at any time. You can also request a review of the process used to make the decision. Contact us for more information about requesting a review.

We consider many factors when assessing a NPPA application. Once the prerequisites are met, we will assess your application against PHARMAC's decision criteria, which we use when making Schedule funding decisions. Even where applications meet the NPPA prerequisites, there is no guarantee that funding will be approved because of other factors included in our decision criteria.

The diagram below outlines our process for considering NPPA applications. This diagram is intended to summarise how we will consider your application, but is not the full and formal process. PHARMAC may vary or add further operational or administrative steps to the process.



11. When can I expect to have a decision on my application?

PHARMAC recognises the need for rapid decisions in some cases, and we will prioritise these applications based on the information provided about the urgency for a decision. Other applications will be assessed in line with the fortnightly NPPA Advisory Panel meetings. For those requiring urgent consideration, PHARMAC is able to consider the situation at short notice, including obtaining the Advisory Panel's advice as appropriate.

Responses will be provided to applicant clinicians as soon as possible following PHARMAC decision.

12. What should I tell my patient about the NPPA Policy?

Your patient is likely to be interested in how the NPPA process works and what to expect. There is a patient-focussed Question and Answer sheet on NPPA available at <http://www.pharmac.govt.nz/nppa> that you can print and give to your patient or provide them the web address for.

13. How do I request a review of a decision to decline a NPPA application?

Please contact PHARMAC for information on the review process for a declined NPPA application.
email: nppa@pharmac.govt.nz - telephone: 0800 660050 - PHARMAC PO Box 10-254 Wellington 6143

Contacting Us

Call us on **0800 66 00 50** (between 9am and 5pm, Monday to Friday),
Write to us at: **PHARMAC, PO Box 10 254, Wellington** – we respond to all letters
Email us at enquiry@pharmac.govt.nz – we respond to all emails

Information Sheets on various PHARMAC topics are available from our website: www.pharmac.govt.nz/patients/infosheets
If you have specific areas of interest (such as consultations, committees or vacancies), visit our website and subscribe to news feeds in the area(s) of interest to you: <http://pharmac.govt.nz/feeds>

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