UPFRONT

Making sense of medicines access criteria

Access criteria, e.g. Special Authorities, are applied to medicines to target funding to groups likely to gain the most benefit. They are generally not intended to guide clinical practice. In recent years, Pharmac has been making changes to access criteria for some medicines, e.g. removing prescriber restrictions and Special Authority renewal requirements. In some cases, access criteria have been removed entirely. The intention behind these changes is to "cut the red tape" and make accessing funded medicines easier, while still balancing the budget. Prescribers ultimately decide whether a medicine is appropriate for a patient; access criteria only define who is eligible to receive that medicine funded.

Not all medicines are funded for all patients who may benefit from them. Unfortunately, that is the reality of a fixed medicines budget and a population with increasing health care needs and complexity. Pharmac regularly assesses applications for funding of new medicines or to widen access to an already funded medicine, but there is still a gap between unmet needs and resources available to address these. While we acknowledge the bigger issues of healthcare funding and delivery models for primary care, it is useful to revise our understanding of what medicines access criteria are, why they exist, how to apply them in your practice and how to explain them to patients.

Access criteria: Explained

In New Zealand, a range of medicines are funded (subsidised) by Pharmac. Most medicines are funded without restriction, i.e. the medicine is funded when prescribed for any patient for any indication regardless of their clinical circumstances. However, in some instances, the funding is directed at certain patient groups, i.e. access criteria apply. Access criteria are restrictions applied to Pharmaceutical Schedule listings that define which patients can receive funded medicines (see: "Methods of access criteria").[1] It does not mean that the medicine is only suitable for these patients.

Pharmac uses access criteria as a targeting tool to ensure medicines are funded for people who are most likely to benefit, and to provide effective medicines budget management.[1] In general, access criteria are not intended to guide clinical practice, e.g. be used to manage safety or other prescribing issues or determine appropriateness of treatment. This should be the responsibility of the prescriber.

Historically, due to limited prescribing guidance being readily available, clinical information was added to Pharmaceutical Schedule listings, e.g. in the form of a clinical note or included as part of specific access criteria. However, the New Zealand Formulary is now available to guide medicine use, and it is generally not within the remit of Pharmac to provide clinical information about how to prescribe or use a medicine unless it is needed to determine the group of people eligible for funding.

Methods of access criteria

Several methods are used by Pharmac to target the funding of medicines to certain patient groups. In a community setting, three types of access criteria are used: Special Authority, Subsidy by Endorsement or Annotation and Specialist Restrictions.[2]

Special Authority (most common): this is an application process in which any relevant practitioner or named specialist requests a specific medicine to be funded for a particular patient. Special Authority criteria define the circumstances under which a patient would be eligible for funding of a particular medicine, e.g. meeting certain laboratory test thresholds, condition severity, other treatments must have been trialled first. Examples include methylphenidate, dulaglutide, empagliflozin and umeclidinium + vilanterol. The Special Authority application and prescribing of the medicine can be done by different practitioners if it is within their scopes of practice, e.g. if a named specialist has applied for Special Authority for a patient, a general practitioner can prescribe the medicine if appropriate.

Subsidy by Endorsement or Annotation: access to the funded medicine requires addition of text on the prescription by the prescriber or pharmacist, e.g. "certified condition". This is a declaration that the patient meets the access criteria listed in the Pharmaceutical Schedule, e.g. an endorsement that the patient has a specific condition, cannot swallow tablets, other treatments have been ineffective or not tolerated, has been taking the medicine prior to a specific date. Criteria tend to be less detailed and specific than Special Authority, but still need to be met to have the medicine funded. Examples include blood glucose diagnostic test meters and strips, ceftriaxone, glycopyrronium powder for inhalation and ketamine.

Specialist Restrictions: access to the funded medicine requires the prescription to be written by, or on the recommendation of, a specialist. This is indicated in the Pharmaceutical Schedule by "Retail Pharmacy-Specialist". This restriction applies to very few medicines used in a primary care setting. In most cases, prescriptions or recommendations can be made by any specialist (including vocationally registered general practitioners), unless specific specialists are named. In practice, these medicines are typically prescribed by practitioners within the relevant specialty. Examples include medicines used in oncology, e.g. etoposide, mercaptopurine (also used off-label for Crohn's disease and ulcerative colitis), and some medicines used for tuberculosis, e.g. isoniazid.

Funding in exceptional circumstances

The Exceptional Circumstances Framework is a method for funding medicines for a small number of patients whose clinical needs are not met via the Pharmaceutical Schedule process. This primarily occurs via a Named Patient Pharmaceutical Assessment (NPPA) process and Special Authority waivers. The Pharmaceutical Schedule process supports funded access for population groups, whereas this Framework exists to fund treatments for individual patients who fall outside of the population, i.e. those who have exceptional circumstances.

The NPPA process provides an avenue for funding medicines that are not listed in the Pharmaceutical Schedule for those who have trialled all possible funded options (or funded options are not clinically suitable for the patient), or whose clinical situation is unusual and outside of those specified in access criteria. Specific principles must be met for funded access to be granted. In 2024/25, 1,353 new NPPA applications were received by Pharmac; 58% (~785) were approved, 9% (~122) were withdrawn and principles were not met in 33% (~446) of applications.[3] Examples of medicines funded due to exceptional circumstances via NPPA have included ciclosporin eye preparations, retinol (vitamin A), alpha tocopheryl acetate (vitamin E) and zonisamide.[4]

Waivers can apply where a patients' clinical circumstances meet the intent of the Special Authority criteria (i.e. patient is within the intended population for whom funded treatment is directed at), but technical requirements of the criteria are not met, e.g. due to concerns about safety or appropriateness. For example, Special Authority criteria require a patient to have trialled a certain medicine, however, they are pregnant and the medicine is teratogenic, therefore is contraindicated. The waiver process may also be appropriate in situations where Special Authority criteria state that a specific test or imaging is required, but is not accessible for the patient. In 2024/25, 603 waiver applications were received by Pharmac; 72% (~434) were approved, 11% (~66) were withdrawn and 17% (~103) of applications were declined.[3]

Recent changes to access criteria

Medicines access criteria can be reviewed over time and are subject to change. Examples of recent changes Pharmac has made to access criteria include:

- **Removal of Specialist Restrictions and Special Authorities** entirely from some medicines, e.g. methotrexate, ezetimibe, rosuvastatin (to be removed from October, 2026)
- **Widening the types of prescribers who can make Special Authority applications** for some medicines, e.g. any relevant practitioner can now make a Special Authority application for infliximab, etanercept, secukinumab and rituximab
- **Removal of Special Authority renewal requirements** from some medicines used for long-term conditions, e.g. psychostimulant medicines for ADHD, febuxostat, LAMA/LABA inhalers, continuous glucose monitors for type 1 diabetes. This means that the Special Authorities are valid without further renewal unless notified and patients can continue to access the funded medicine for as long as it is clinically indicated.
  - In other cases, Special Authority approvals are only valid for a certain period of time, e.g. six months to two years, before a renewal application is required to confirm that treatment remains appropriate and the patient is benefiting from the medicine

What are the implications of widened access criteria for primary care?

These changes to prescriber restrictions, eligibility for and duration of funding, are intended to remove barriers to accessing treatment as well as ease administrative burden associated with prescribing. However, access criteria only define the groups of people for whom a medicine would be funded; whether the medicine is appropriate for a particular patient and how it is prescribed should be determined by the prescriber. A prescriber's scope of practice will also determine if it is appropriate for them to prescribe certain medicines; the ability to apply for a Special Authority should not be assumed to mean that the medicine is within the prescribers scope or that they have to prescribe it.

Changes to access criteria are not intended to move responsibility for prescribing medicines from specialist services to general practices, but rather it provides clinicians who are experienced or confident in prescribing a certain medicine, or practices that wish to offer specific treatments in the community, the ability to do so without restriction.

In some cases, there will be secondary care specialists who previously had exclusive responsibility for prescribing a certain medicine, who will divert this responsibility to their primary care colleagues. But ultimately, a clinician should not prescribe any medicine unless they are satisfied that it is the right treatment for the patient in front of them and they are knowledgeable in its use. The bottom line is that medicines access criteria are an administrative tool, not a clinical instruction.

For prescribing information and other clinical guidance, prescribers should refer to sources such as the NZF, bpac[nz] and other recognised evidence-based clinical information.

Article supported by Pharmac

N.B. This Upfront perspective was written by bpac[nz]; Pharmac reviewed the article to check accuracy. All other commentary is from bpac[nz] and does not necessarily represent the views of Pharmac.

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