Patient self-funding offers to access medicines: Drug and Therapeutic Committee considerations

Drug and Therapeutic Committee (DTC) assessment of medicine applications including those involving patient-self-funding should be based on Quality Use of Medicines principles. Access to and use of a non-formulary medicine must involve assessment of effectiveness and safety in the relevant clinical context and determination of a favourable benefit: harm ratio for the individual patient, without consideration of that patient's ability to pay. The CATAG Guiding Principles for the Quality Use of Off-label Medicines, particularly Guiding Principle 2, describe how medicines can be assessed to determine appropriateness for use.[1] Although the practice of patient self-funding for medicines is not endorsed by NSW TAG, if it does occur after robust local evaluation, detailed explanation regarding the conditions of use should be documented in the medical record. As with any non-routine off-label use of medicines, written informed consent should be obtained.[1]

Background

Applications for non-formulary medicines that involve patient self-funding* offers are not limited to Medicines Access Program-type arrangements, where they are often referred to as Cost Share Programs. The CATAG Guiding Principles for Medicines Access Programs provide guidance on how DTCs should manage participation in Cost Share Programs.[2] CATAG does not encourage such arrangements, advocates negotiations with the supplier for a reduced medicine price using the appropriate procurement process and recommends diligent risk assessment and mitigation by the organisation if a patient self-funds medication use.

In 2015, the NSW TAG Editorial Committee recognised that guidance may also be useful for those applications that are not part of a formal Cost Share Program. Consultation with NSW DTCs identified variation in how DTCs were managing patient self-funding requests to access medicines.

Issues related to patient self-funding requests to access medicines

Consultation and discussion by the NSW TAG Editorial Committee identified the following actual or potential issues, some of which were highlighted in a recent local publication[3]:

- **Quality Use of Medicines**
  - Provision of medicines that are not efficacious, safe or cost-effective
    - Patient /family or health care practitioner request a medicine that is unlikely to be effective and hence hospital expenditure not justified; however, the specialist has no objection to treatment supervision and medicine administration (if parenteral).
    - Some evidence for effectiveness exists but price is unaffordable by the hospital and no Medicine Access Programs are available
  - Evaluation by DTC and pharmacy processes for quality assurance may be bypassed via:
    - Hospital departments participating in patient self-funding arrangements omitting assessment by the DTC or pharmacy department processes
    - Advocacy by non-clinicians or patient support organisations including the provision of guidance to patients on how to access non-registered or non-PBS-subsidised medicines that may not include explanation and consideration of QUM principles or meet quality assurance standards, e.g. patient importation of medicines of sub-optimal quality, questionable cold chain supply.

* Patient self-funding refers to a patient's out-of-pocket expense not reimbursable through private health funding

- **Inequitable access to medicines**
  - Across the jurisdiction:
    - Between those who can and cannot afford to pay
    - between inpatients and outpatients, creating perverse incentives such as hospital admission to access medicines
  - Between jurisdictions – resulting in DTC-shopping by patients and/or prescribers to access medicines

- **Financial**
  - Institutional liability for medicine price after patient refusal to pay, despite initial agreement
  - Institutional liability for price of imported medicine in a patient who dies prior to medicine arrival
  - Ethics regarding potential economic harm to patients[3]
  - The need for DTCs, and possibly the Hospital/LHD Executive, to consider affordability and equity issues for future patients with the same or similar clinical circumstances if a favourable benefit: harm ratio has been determined by the DTC
  - Crowd-sourcing for medicines funding
  - Lack of clarity regarding subsidisation via private health insurance- pharmaceutical extras if the patient attends a private hospital which has a contract with the pharmaceutical company or the patient is an outpatient or attends a community pharmacy
  - Potential for patients to import the medicine at a lower price than that available in Australia

Recommendations

The NSW TAG Editorial Committee recognises that these considerations regarding medicines access and use also apply to the primary care setting and non-hospital prescribers, including access to non-PBS medicines or access to medicines for indications not supported by the PBS. The following recommendations are made:

- All prescribers have a responsibility to provide robust evaluation of Quality Use of Medicines issues prior to an assessment of the patient's ability to pay.
- DTCs should consider equity of access issues after a robust QUM evaluation and determination of favourable benefit: harm ratio for the individual patient; noting that future supply to another patient under similar conditions, should be provided whether self-funded or not.
- All patients must have a clear understanding of the potential benefits and harms (including financial loss) to them of using the medicine.
- Written informed consent should be obtained, consistent with usual practice for off-label medicines use, with criteria for use and funding agreement documented in the medical records.
- The patient should be informed of the potential for:
  - Sharing de-identified information with other relevant health care professionals or organisations; and/or
  - Discontinuation of medication if no therapeutic response or adverse effects occurs, with accompanying documentation in the medical records.

References

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