# Improving Medicines Governance Through a Streamlined Individual Patient Use (IPU) Approval Process

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## BACKGROUND:

A medicines formulary in place across 6 public hospitals is managed by a Territory wide Drugs and Therapeutics Committee (DTC).

## DESCRIPTION:

A review of non-formulary approval processes was conducted in 2016 following feedback from senior clinicians that the existing processes were inefficient and ineffective at managing the growing number and complexity of requests.

Clinicians perceived the process to be cumbersome and lacking transparency. The process did not allow for a rigorous review of the medicine including; evidence, cost, and advantages over formulary equivalents.

## ACTION:

A formulary policy and tiered approval process was developed in consultation with key stakeholders. The new process involved the Director of Pharmacy, a subcommittee of medical specialists from DTC, and the Executive Director of Medical Services, with pathways based on evidence and cost. New IPU forms were developed to assist clinicians with providing appropriate justification and an electronic database was implemented to prompt consideration for formulary addition. A change management and communication plan was developed and the new process was implemented in December 2016.

Non Formulary Database

HRN First Name Last Name Search

| ate Approved | Form type | Drug Name | Indication | Expiry date | Approval Body | Hospita |
|---|---|---|---|---|---|---|
| 24/10/2019 | IPU initiation – outpatient | Tofacitinib | UC | 24/04/2020 | Director of pharmacy | RDH |
| 23/10/2019 | IPU continuation – outpatient | Filgrastim | Valganciclovir induced neutropenia | 23/11/2019 | Director of pharmacy | RDH |
| 23/10/2019 | IPU initiation – outpatient | Dulaglutide | Type 2 Diabetes | 23/10/2020 | Director of pharmacy | RDH |
| 22/10/2019 | IPU initiation – inpatient | Neisseri meningitidis vaccine | Prevention in immunosuppressed patient | 22/12/2019 | Director of pharmacy | RDH |
| 21/10/2019 | IPU initiation – both | Fentanyl lozenge | palliative care pain | 21/01/2020 | Head of department | ASH |
| 21/10/2019 | IPU continuation – inpatient | Desvenlafaxine | depression | 21/10/2020 | Clinical pharmacist/registrar | ASH |
| 18/10/2019 | IPU initiation – inpatient | Ketamine Wafers | Analgesia reduction program | 21/10/2020 | Director of pharmacy | RDH |
| 17/10/2019 | IPU initiation – both | Sildenafil | Scleroderma Refractory Reynauds | 17/10/2020 | Head of department | ASH |
| 17/10/2019 | IPU continuation – outpatient | tolvaptan | SIADH; symptomatic hyponatraemia | 17/04/2020 | NTDTC subcommittee | RDH |
| 16/10/2019 | IPU continuation – outpatient | Omalizumab | indolent systemic mastocytosis | 16/10/2020 | NTDTC subcommittee | RDH |

Figure 1: IPU Database

## EVALUATION:

- Clinician feedback was sought 12 months post implementation. A survey was distributed to medical staff (332), and pharmacists (33). 11 responses were received (5 medical, 6 pharmacists). The majority (82%) understood why the change needed to occur and (73%) were satisfied with the information provided.
- Non-formulary medicines expenditure initially increased in 2016/17, then steadily declined, with 2018/19 expenditure approximately 71% of 2015/16 expenditure.
- In the 30 months post implementation, 2128 approvals were processed, and 21 of 61 (34%) medicines flagged via the database have progressed to formulary addition.

## IMPLICATIONS:

The review has improved governance over non-formulary medicines use, increased transparency and review by a multidisciplinary team of clinicians. It has also allowed a more proactive mechanism for listing medicines on the formulary to respond to changes in practice.

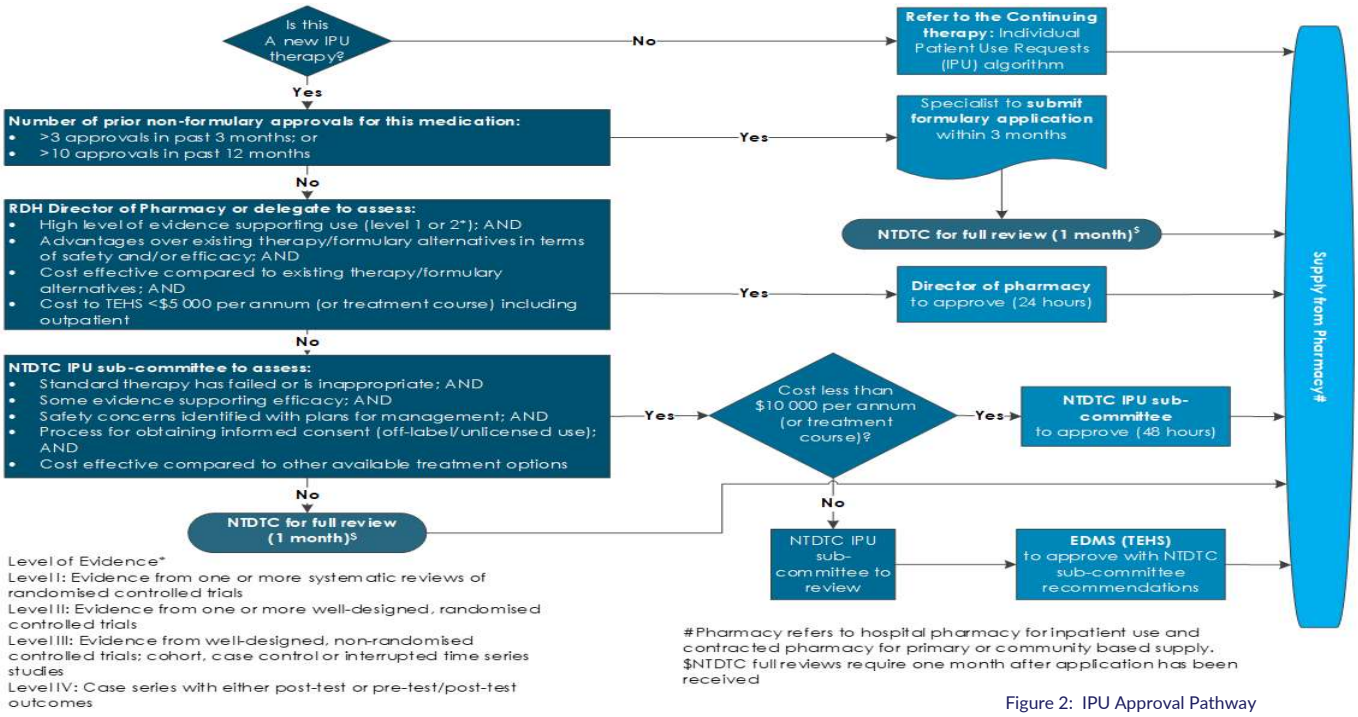


Figure 2: IPU Approval Pathway