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PREAMBLE

Non-Formulary (NF) drug use refers to any drug or natural health product not listed as a regular benefit (F), Restricted Use Benefit (RS), or Special Authorization Benefit (SA) on the Calgary Type A Continuing Care Home (CCH) Formulary. Additionally, it applies to any Formulary product not utilized in accordance with Formulary use criteria or guidelines.

An NF drug request may be necessary when:

- Other pharmacologically or therapeutically similar Formulary drugs have been tried unsuccessfully
- Specific laboratory or medical investigations indicate that the drug is the clear choice
- There is no viable Formulary alternative
- There is a valid clinical reason to use a Formulary drug not in accordance with the Formulary listing criteria

NON-FORMULARY DRUG FUNDING PROCESS

For a summary, refer to [Table 1. Non-Formulary Workflow](#)

Integrated Supportive & Facility Living (ISFL) Drug Management may be involved at any point in the process.

1. When prescribing, whenever possible, a formulary drug is chosen.
2. Upon receipt of a prescription for a NF drug, the pharmacist contacts the prescriber to discuss viable Formulary alternatives as necessary.
3. The pharmacist and prescriber should agree there is no viable formulary alternative and there is reasonable rationale to justify the use of a NF drug, an application for NF drug funding request may be made to ISFL Drug Management.
4. In the rare event the pharmacist and prescriber disagree on whether there is a suitable Formulary alternative, the clinical context and nature of the disagreement is included on the NF request for consideration and deliberation.
5. The clinical pharmacist completes **FPP-3a - Non-Formulary Drug Request** form with the relevant resident and clinical information, completes the attestation, and submits to ISFL Drug Management via email to cc.drugmanagement@albertahealthservices.ca or fax to (403) 943-0232 for review and a decision. Alternatively, requests may be submitted by the prescriber.

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6. The NF request will be assessed by an ISFL Pharmacist for a decision. The P&T Medical Chair or other members of ISFL Drug Management may be consulted at any point during the NF review process. The following factors will be considered in determining whether the use of the NF product will be funded:
- Indications for use. Applications for off-label use must include evidence or citations to support the application.
 - Rationale for using the NF drug compared to Formulary alternatives or Formulary criteria.
 - Consideration of lower cost medications, Formulary or otherwise.
 - Previous trials of formulary alternatives (or reasonable explanation as to why formulary alternatives are not suitable). Previous trials are expected to be of adequate duration and dose to allow for proper assessment of efficacy.
 - Laboratory or diagnostic evidence that supports the NF drug is the drug of choice
 - Resident-specific factors such as financial hardship
 - Additional clinical judgment or treatment experience from prescriber or pharmacist, if applicable.
 - Expected outcomes and measures of successful therapy.
7. The ISFL Pharmacist decides whether the request is approved or declined. Additional parameters such as duration of approval, outcomes, trial status, funding limits may be included in the decision.
8. Ongoing or continuing funding may be subject to a renewal request as indicated on the initial decision.
9. If an NF request is declined by ISFL, the NF product shall not be funded by ISFL. Provision of the NF product may still occur if the pharmacy provider is able to secure alternate funding via the resident or their agent, alternate insurance, or a combination thereof. Alternatively, it can be supplied by the resident or their agent in alignment with the home policies and procedures. If an alternative funding or supply source is not available, the care team must consider other therapeutic alternatives.

Monitoring

NF drug utilization will be monitored and reviewed by ISFL Drug Management. A summary of NF drug usage will be reviewed by the P&T Committee as required.

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Grace Period Funding

To support safe transitions, the Committee allows for a grace period of up to three weeks for non-compliant drug use upon admissions. The grace period applies to most prescription drugs, including those with therapeutic substitutions. In exceptional situations where a 3-week period is insufficient to allow for drug changes, the period may be extended to the initial care conference or quarterly medication review, to a total duration of 6 weeks from the admission date. During the grace period, ISFL will temporarily fund a drug not listed on the Formulary or when used outside listing criteria. If an NF application is not received and approved to continue funding past the grace period, funding will cease for the drug in question. The prescriber and/or contracted pharmacy provider are expected to have a proactive discussion with the resident or their agent regarding funding issues and solutions.

Exceptions to Coverage Under the Grace Period and NF Funding

High cost NF drugs should be prioritized for funding assessment and reviewed upon admission. Over-the-counter products and medical devices, unless listed on the Formulary, are not eligible for coverage under the Grace Period or NF funding. The resident or their agent will need to pay for these products as arranged through the contracted pharmacy provider.

Therapeutic Substitution

To streamline drug therapy, orders for certain NF drugs may be routinely substituted (also known as therapeutic substitution) to a different drug that is considered therapeutically equivalent. The Committee approves these substitutions.

The rationale for therapeutic substitutions may vary by drug product, but typical motivating factors for any given product may be:

- ease of drug regimen
- to decrease the number and variability of available drugs
- cost of therapy
- clinical effects are similar or non-inferior to the original prescribed therapy
- to support drug shortage situations

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During the grace period following a resident's admission, the pharmacist may use this time to assess and determine the appropriateness of any therapeutic substitution, and not feel compelled to immediately change therapy during medication reconciliation. Any modification made to the prescription by the pharmacist must be documented and communicated to the pertinent team member, and done in alignment with professional standards of practice

At any time, if a substitute product is considered clinically inappropriate for the resident, the substitution should not take place, and the pharmacist should consult with the resident's medical practitioner to determine the most appropriate therapy and apply for NF funding as necessary.

Note: Therapeutic substitutions are generally mandatory unless a clear clinical rationale supports the continued use of the originally prescribed drug. Any exemption requires application under the NF process and may or may not be approved past the grace period.

Alternate Sources of Drug Funding

Type A CCH drug funding does not apply to drug products where the costs are covered by specialized drug benefit programs through Alberta Health. <https://www.alberta.ca/specialized-drug-benefits>

A resident may have alternate sources of funding such as Alberta Health drug benefits (e.g. Seniors, Palliative, Assured income for the Severely Handicapped), federal drug benefits, pharmaceutical-funded patient-support programs and/or private insurance, all of which may be used to assist with funding a NF drug provided the drug is eligible for funding under the respective program. If no alternate funding is available and coverage is denied through the **FPP-3a - Non-Formulary Drug Request**, the resident will need to pay for the drug as arranged through the contracted pharmacy provider or change to a Formulary option.

Appealing a declined NF Funding Decision

If an NF request is declined, the pharmacist and medical practitioner should review the reasons for denial and evaluate alternative options. If the clinical team believes there is justification to do so, the decision

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may be appealed. Appeals can be made by email by resubmitting the application, including a rationale for challenging the decision. Any additional relevant information and evidence not previously submitted must be included for consideration.

HIGH COST NON-FORMULARY DRUGS

For a summary, refer to [Table 2. High Cost Non-Formulary Workflow](#)

High cost NF drugs may be medically necessary for specific indications, where a lower cost alternative, either on or off formulary, may be not available or appropriate.

High cost NF drugs are defined as those exceeding \$250 per month or \$230 per dispense, or as otherwise determined by ISFL Drug Management.

Process for High Cost NF Drugs

When a High Cost NF drug is prescribed and there is no viable formulary alternative or there is no funding available from alternate sources (e.g. private insurance plan), the pharmacist contacts the prescriber, and the resident or their agent to make them aware that further clinical assessment may be required for ISFL funding to be considered.

If the resident's medical history is limited or unavailable, a care team member may need to contact the original prescriber for additional information.

A. Situations with no alternate insurance or funding

When completing the NF Drug Request Form, the following information is required for a comprehensive assessment.

1. Clinical history and supporting documentation
 - Detailed baseline health status (prior to starting the high cost drug) such as laboratory results, outcome or other measurement scales, etc.
 - History of non-pharmacological treatments and outcomes.
 - Prior drug trials and responses to treatment.
 - Notation that there are no other viable clinically appropriate alternatives (including formulary drugs).

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- Date the high cost drug started, any dose adjustments with corresponding dates.
 - Evidence that the high cost NF drug has benefitted the resident including response details.
 - Most recent assessment results including date of last in-person/virtual assessment
 - Monitoring parameters to support ongoing use and success indicators.
 - Specialist follow-up.
 - Previous or alternate funding support.
2. Information on current health status:
- a) An on-site assessment of the resident’s current health status and potential beneficial impact of the high cost NF drug may be required for funding consideration and may include:
- Review of current documentation which reflects the resident’s health status such as: RAI-MDS scores, Frailty Scale, Goals of Care Designation, Advanced Care Planning, Serious Illness Conversations, Flacker Mortality Index, etc.
 - Review of the high cost NF drug risks / benefits and how it aligns with the resident’s Goals of Care Designation and current health status. This may include a multidisciplinary medication review.
 - Completion of outcome assessment forms for select drugs (e.g. Disease Activity Score (DAS28) when biologics are prescribed for rheumatoid arthritis).
 - Anticipated duration of use and endpoints defining potential drug discontinuation.
 - Contact the Site Lead Medical for additional support if needed.
3. Funding Evaluation
- Requests will be reviewed on a case-by-case basis by ISFL Drug Management and when necessary, be referred to the P&T Committee or clinical expert for review.
 - Additional information may be requested.
 - Coverage may be temporary and include specific monitoring requirements for ongoing funding.
 - ISFL will notify the clinical pharmacist when a funding decision has been made.
 - If coverage is declined, the care team will review other options with the resident or their agent.
4. Reassessment
- Should there be a significant change in a resident’s health status, a reassessment must be initiated to review the risk versus benefit of ongoing treatment with the high cost NF drug

B. Situations with alternate insurance or drug plan

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1. In cases where the high cost NF drug is an eligible benefit under the resident’s alternate public or private insurance or drug plan/program, the drug benefit is to be utilized prior to requesting NF funding.

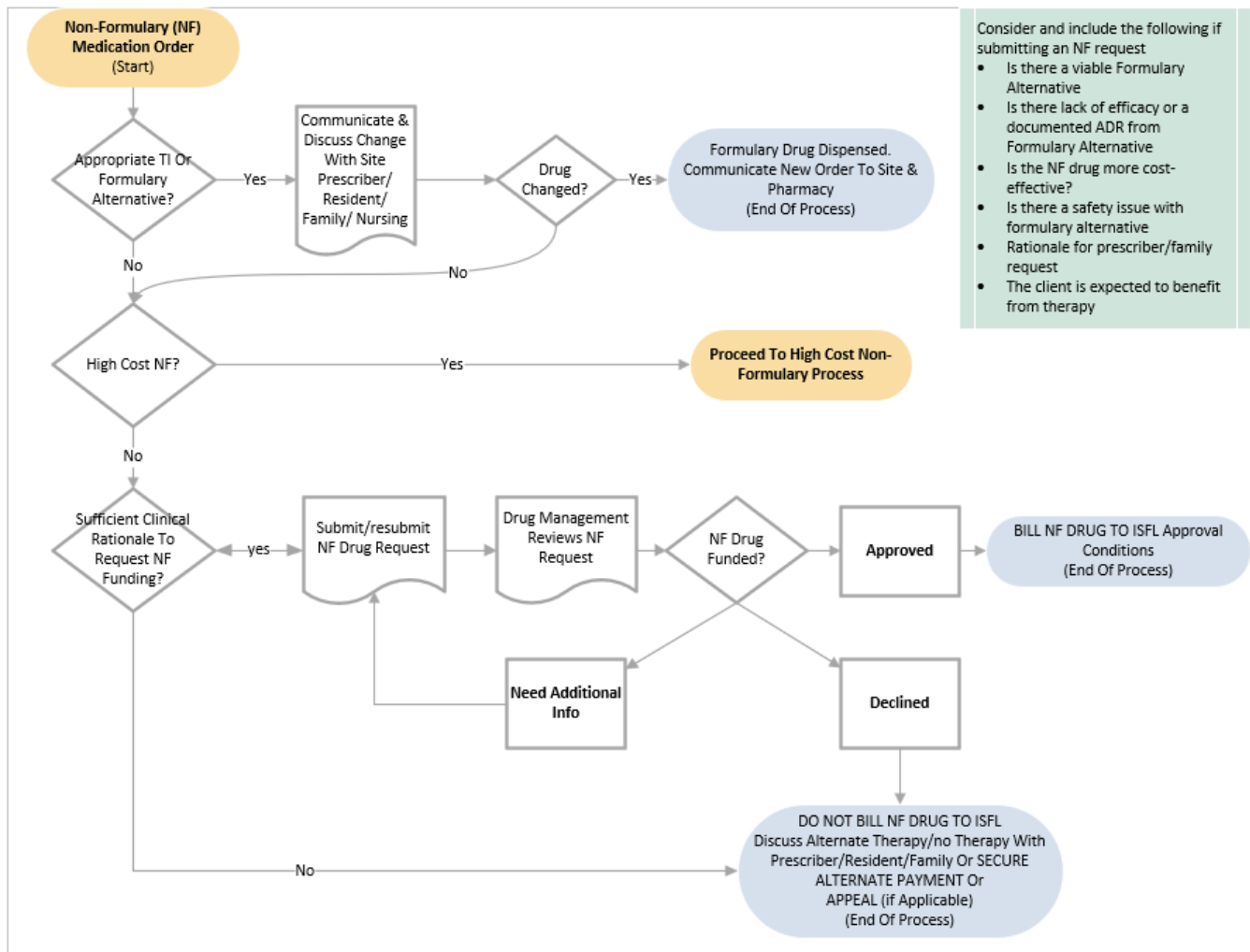
Examples of alternate insurance or drug payment

- Alberta Public Insurance Plans (e.g. Assured Income for the Severely Handicapped, Coverage for Seniors (Group 66), Non-group coverage (Group 1), Palliative Care Health Benefits), Specialized Drug Benefits).
- Federal Public Insurance Plans (e.g. Non-insured health benefits for First Nations and Inuit (NIHB), Veterans Affairs Canada)
- Private insurance plans (e.g. Alberta Retired Teachers’ Association, Green Shield)
- Drug programs sponsored through the drug manufacturer (e.g. compassionate funding)
- Resident funded

2. If additional NF drug funding is necessary to cover all or a portion of a drug cost, the clinical pharmacist submits the **Non-Formulary Drug Request** form with the required high-cost NF drug information outlined in section A *and* includes the rationale for requesting additional funding support.

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Table 1. Non-Formulary Workflow



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Table 2. High Cost Non-Formulary Workflow

