NCPE Budget Impact Guideline

Version 1.1

13 April 2026

NCPE
National Centre for
Pharmacoeconomics, Ireland

Introduction to the NCPE Budget Impact Guideline

The purpose of the NCPE Budget Model Guideline is to provide guidance on the conduct of a drug budget impact analysis (BIA). This guideline is supplementary to the Rapid Review and Full HTA Submission templates, and details what information is required, and how it should be presented, to ensure full transparency when reporting BIAs. The NCPE requires that the BIA must be conducted using the NCPE Budget Impact Model Template and that a narrative analysis is reported in the Applicant Submission Templates (Section 5 for Rapid Reviews and Section 7 for full HTAs). Where either of these requirements are not provided in full, the submission will be sent back to the Applicant and a re-submission will be required. Therefore, these guidelines should be consulted when completing the mandatory Budget Impact Model Template for all submissions. Specific guidance on the inclusion of drug costs is available from the NCPE Guideline for Inclusion of Drug Costs in Pharmacoeconomic Evaluations.

Version Control

The version control table outlines any key changes which were made to the Budget Impact Model Guideline since the publication of the last major version (V 1.0), in addition to changes which are in progress. Please contact bim@ncpe.ie if you wish to enquire about any of these changes.

Version	Date	Description of key changes
1.0	08/01/2025	First publication of the Guideline
1.1	13/04/2026	Inclusion of guidance on how to vary the Framework Rebate in scenario analyses. Updated wording throughout the guideline to reflect changes made to v2.3 of the NCPE Budget Impact Model Template v2.3 (See Version Control within the template for further details). Inclusion of guidance on use of age-standardised prevalence and incidence rates in the NCPE Budget Impact Model.

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List of Abbreviations

BIA	Budget Impact Analysis
BIM	Budget Impact Model
CDS	Community Drug Schemes
CEM	Cost-effectiveness model
CIC	Commercial-in-confidence
CPU	Corporate Pharmaceutical Unit
CSO	Central statistics office
DSA	Deterministic sensitivity analysis
FAC	Factual accuracy check
FASPM	Framework Agreement on the Supply and Pricing of Medicines
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
HT	High Tech
HTA	Health Technology Assessment
INN	International non-proprietary name
IPHA	Irish Pharmaceutical Healthcare Association
NCPE	National Centre for Pharmacoeconomics
PtW	Price to Wholesaler
PAF	Pricing Application Form
PAS	Patient Access Scheme
RCT	Randomised Controlled Trial
RDI	Relative dose intensity
RR	Rapid Review
SPC	Summary of Product Characteristics
ToT	Time on treatment

Instructions for Applicant Companies

The structure of this Guideline is designed to align with the format of the NCPE Budget Impact Model (BIM) Template, such that it will follow the sequential order of the sheets presented in the model. Additional guidance relevant to the Budget Impact Analysis (BIA) section of the Rapid Review Submission Template (Section 5) and the Full Health Technology Assessment (HTA) Submission Template (Section 7) is provided under each subheading. Before submitting the BIA and the BIM, please ensure that all documents outlined in the Document Checklist are available.

Please note that the purpose of the BIM template is to ensure consistency in reporting of the BIA. The BIM is designed to accommodate submissions across several disease areas. However, it is acknowledged that every RR and HTA is different. Therefore, the NCPE BIM template may be adapted where necessary. Required changes should be clearly documented and should be easily validated by the NCPE Review Group.

Scope of the Budget Impact Analysis

Perspective

The BIA should be conducted from the perspective of the publicly-funded health and social care system in Ireland.

- In Ireland, the Health Service Executive (HSE) represents the publicly-funded health and social care system. Therefore, only direct costs relevant to the HSE should be included in the BIA.
- The perspective of the base-case BIA should align with the perspective of the base-case cost-effectiveness analysis.
- Broader perspectives may be explored in scenario analyses and should align with scenarios conducted in the cost-effectiveness model (CEM).

Intervention

The intervention should describe the drug, or combination of products, for which reimbursement is being sought.

- The intervention described in the BIA should correspond to that described in the CEM, including the same assumptions regarding dose, frequency, route of administration, duration of treatment, etc.

Comparator(s)

The comparator(s) should reflect the current standard of care in Ireland.

- Comparator(s) included in the BIA should correspond to that described in the CEM, including the same assumptions regarding dose, frequency, route of administration, duration of treatment etc.
    - Where the comparators in the BIM differ from those in the CEM, a clear rationale must be described in the Applicant Template. If the Review Group considers that the rationale is not sufficiently justified, and comparators are

either inappropriate or have been omitted, the Applicant will be requested to provide an updated BIA. Combination treatments are considered as one comparator.

- Disease areas can experience rapid therapeutic evolvement. There may be multiple drugs, licensed for similar indications, progressing through the reimbursement process at any given time. Only drugs which are reimbursed for the indication under review, at the time of assessment, should be considered in the base-case BIA.
- The timing for the availability of new drugs, even those for which a full HTA has been completed, is subject to substantial uncertainty. Therefore, it is recommended that the potential for emergence of other new comparators (not reimbursed at the time of assessment), including generic or biosimilar drugs, is explored in scenario analysis.
- Unlicensed drugs, and drugs used off-licence, should also be included as relevant comparators if they are part of standard of care.

Time horizon

The time horizon should incorporate estimates for five full calendar years.

- The time horizon aims to capture the budget impact up to the timepoint where patient numbers are expected to be stable, with fluctuations primarily driven by changes in prevalence and incidence. This is assumed to be captured by five full calendar years from the date of submission.
- The exact years to be considered in the assessment can be found in the BIM. These should not be modified by the Applicant. Where the year range in the BIM has been inappropriately modified, the Applicant will be requested to submit a new BIM.

Scenario and sensitivity analyses

It is recommended that scenario analyses and sensitivity analyses are conducted alongside the base-case analysis to explore the key uncertainties in the assessment.

- Scenario analysis and sensitivity analyses should be presented where there is particular uncertainty regarding an assumption or a parameter.

- Following publication of the Framework Agreement on the Supply and Pricing of Medicines (FASPM) 2026 to 2029, as standard, a scenario should be provided whereby a Framework Agreement Rebate of 5% is applied to relevant new medicines. This aligns with the agreed rebate for 2029.
- Additional uncertainties which may be of interest to the Review Group are highlighted in this guideline. However, the Applicant may present additional scenarios as required.
- The Applicant should conduct sensitivity analysis by adjusting key parameters to reflect plausible bounds.

Sources of Evidence

- A systematic literature review for inputs to the BIA is not mandatory. However, all inputs used to inform BIA estimates should be obtained using a transparent and systematic approach.
- Estimates should be informed using Irish sources, where possible. The generalisability of the evidence to the Irish setting should be contextualised in Section 5 (in Rapid Reviews) or Section 7 (in full HTAs) of the Applicant Template.
- All efforts should be made to obtain current estimates where possible. Data from the most recent year available should be used.
    - Drug costs are regularly published in sources such as the HSE Price Realignment Files and HSE Reimbursable Items.
    - In some circumstances, it may be appropriate to extrapolate data from previous years to the relevant timeframe in the BIM. Where required, please inflate non-drug costs to the base year in the model using appropriate methods, such as those described in the Health Information and Quality Authority (HIQA) Guidelines for the Economic Evaluation of Health Technologies in Ireland.
- The NCPE recognises that there may be a paucity of published evidence for some model inputs. In exceptional circumstances, internal company estimates may be used. Where this data is applied, the reference material must be included in the

submission dossier.

- Clinical opinion may be used to mitigate uncertainty with BIA estimates, but should not be used as a substitute for an appropriate reference.

Referencing

- Please note that the quality and validity of supporting references will be assessed by the NCPE Review Group. Where the referenced values are not clear, or are not available from the identified reference, this may lead to unnecessary delays in the appraisal process.
- As outlined in the Applicant Template, a PDF version of all references must be included in the electronic submission dossier. Each reference must be clearly identifiable by the file name.
- In submitted references, the relevant value used in the BIM should be highlighted in colour within the primary reference source. Where the exact percentage or number is not presented in the reference, the calculation used to derive the estimate should be presented in the BIM.
- In the BIM, references should also be detailed in the indicated cells.

Document Checklist

When conducting a BIA for either a Rapid Review or full HTA the following items are required:

1. The **current version** of the relevant Applicant Template, as published on the NCPE website (available for full HTAs here; available for Rapid Reviews here);
2. The **current version** of the NCPE BIM, as published on the NCPE website (available here).
3. Where a first-time application for reimbursement is made, the **Pricing Application Form** (PAF) should be provided, to permit validation by the NCPE Review Group. Otherwise, the Applicant may reference the relevant HSE Price Realignment File.

4. **References** for all costs and assumptions applied in the BIM.

Please note that both the Applicant Submission Templates and NCPE BIM Template are subject to updates, to facilitate evolution of NCPE processes. It is necessary to check that the most up to date versions of both documents are used to ensure adherence with NCPE requirements. The Review Group will not accept submissions presented in older versions of the template past the date specified on the NCPE website.

Guidance for estimating the Budget Impact

1. Patient Population

The patient population refers to a specific group of patients who share a common set of characteristics based on a particular health condition.

- The eligible patient population is defined by the full licensed therapeutic indication of the intervention under assessment. **The base case BIA should reflect the eligible patient population.** The NCPE Review Group will request resubmission of a BIA where the eligible patient population has not been used to inform the base case.
- The treated population refers to the proportion, if applicable, of eligible patients expected to receive treatment with the intervention, or any of the comparators.
- Substantial evidence must be provided to justify where a difference exists between the treated and eligible populations, as a result of patient factors, capacity constraints, etc.
    - In exceptional circumstances, wherein a subpopulation of the full licensed therapeutic indication is deemed appropriate, a scenario analysis considering restriction to a subpopulation of the eligible patient population is required.
    - The subpopulation should be clinically relevant, clearly defined, and easily identifiable in clinical practice. Identification and definition of the subpopulation should be supported by published clinical evidence and

validated by clinicians in Ireland.

- Where the NCPE Review Group considers the restrictions to be inappropriate, this will be communicated to the Applicant and a resubmission may be requested.
- The eligible population and the treated population, should be estimated using a top-down approach, supported using a variety of data sources. This should consider the following:

Estimation of the eligible population in the BIM

- The prevalent population refers to the number of patients who have a specific disease, condition, or health-related event at a particular point in time.
- The incident population refers to the number of patients who develop a specific disease, condition, or health-related event during a given year.
- The Applicant should consider whether the prevalence or incidence rate is age-standardised (i.e. is reflective of the entire population, not just adults, children, etc). In some circumstances (e.g. a disease that occurs predominantly in the adult population), application of an age-standardised rate to a proportion of the entire population (e.g. adults only) may result in an underestimated population. In such cases, it is generally appropriate to estimate the number of patients with the disease by applying the age-adjusted incidence rate to the entire population in the BIM.
- The incident and prevalent population may be appropriately estimated in several ways, including:
    - Applying a referenced prevalence or incidence estimate to Central Statistics Office (CSO) Irish population projection estimates.
    - Referencing a nationally representative database. Referencing estimates from the literature. These must be reflective of the year specified in the BIM and be generalisable to the Irish setting.
- It is important to consider the potential for an increase or decrease in patient numbers over the time horizon of the BIA. This may be explored in scenario analysis.
- In general, it is the preference of the NCPE Review Group that both the incident and prevalent population are considered in the eligible population estimates. If there is a strong justification to account for only incident or prevalent patients, this should be

described in full in the Applicant Template. Where the population has been inappropriately restricted, the NCPE Review Group will request an updated model inclusive of both the incident and prevalent population.

- The flow of incident to prevalent patients should be considered where patients receive treatment for a duration of greater than one year.
- Mortality should be presented as the proportion (percent per annum) of patients with the condition, defined by the prevalence and incidence estimate used, who die within a given year. If this proportion is negligible, mortality may be omitted from the BIA. Where there is uncertainty in the mortality rate estimates, this may be explored in scenario analyses.

Market Share

- Market share refers to the proportion of the treated population expected to receive any of the treatments included in the model (i.e. the intervention and comparator(s)).
- Market share estimates are required for two scenarios:
    - The market share **without the intervention,** which should consider the distribution of the current standard of care therapies (i.e. comparators) in Ireland.
    - The market share **with the intervention,** which should consider introduction of the new intervention and resultant displacement of the current standard of care.
- Assumptions underpinning cost offsets due to displacement of other drugs in net drug-budget impact calculations are often particularly unpredictable. The magnitude and persistence of these cost-offsets in clinical practice should be carefully considered.
- Market share estimates should be informed by data on current utilisation of comparator drugs in Ireland, wherever possible. International market share data may be used in exceptional circumstances, supported by justification which addresses the potential for differences between markets, as information from a different market may not be directly transferable to Ireland.

- A market share of 100% should be assumed where there is evidence of a high unmet need in the patient population, and a reasonable expectation that there will be a general preference for the new intervention over existing treatment options.

Discontinuation rates

- Use of a discontinuation rate is optional in the model. The model is structured in such a way that where an annual discontinuation rate is applied, the model applies half of the assumed treatment cost (e.g., if an annual treatment cost is applied, the model will apply costs for six months of treatment). This is based on the assumption that, on average, patients receiving treatment will discontinue halfway through the intended treatment duration. The Applicant should give consideration to whether a discontinuation rate is applicable to the disease area.
- A discontinuation rate should not be applied where:
    - There is evidence available to support a mean duration of treatment.
    - Where the discontinuation rate produces a time on treatment that is not in line with clinical evidence.
    - The duration of treatment (in the Drug Acquisition Costs sheet) is informed by a mean duration of treatment or modelled time to treatment-discontinuation; a discontinuation rate should not be applied, to avoid double-counting.
- Drugs licensed for chronic diseases (e.g. asthma; epilepsy) may be taken continuously and are potential life-long treatments. However, a proportion of patients may discontinue treatment for a variety of reasons. For such drugs, it may be appropriate to apply an annual discontinuation rate.
- The discontinuation rate should be fully justified in the Applicant Submission Template, and accompanied by an appropriate reference. Generalisability of this assumption to the Irish setting should also be explored, particularly where the discontinuation rate is derived from a clinical trial.

2. Drug Acquisition Costs

Drug Acquisition Costs reflect the total drug cost to the HSE, inclusive of:

- Price to Wholesaler

- Wholesale mark-up
- Framework Agreement Rebate (if applicable)
- Value-added Tax
- Pharmacy fees (if applicable)

- The base case should be reflective of publicly-available prices.

Drug Acquisition Costs

- The NCPE Guideline for the Inclusion of Drug Costs should be referenced to inform the drug acquisition costs.
- Where there is uncertainty about the funding arrangement, this should be agreed with the HSE Corporate Pharmaceutical Unit (CPU) before submission of the Rapid Review or HTA.
- Non-drug costs should not be included in Drug Acquisition Costs; these may be included in 'Additional Costs/Cost-offsets' if appropriate.
- Where the dose can be constituted using combination formulations, or using a combination of different formulations (including those of different strengths), the price to wholesaler should reflect the lowest costing combination available. An exception to this may occur where the lowest costing combination does not represent what would be practical to use in clinical practice, based on patient acceptability (e.g. use of a lower-cost combination of five 10mg tablets rather than one 50mg tablet).
- If a number of different products are available for one comparator drug (e.g. generics), the price of the lowest cost product should be used.

Framework Agreement Rebate

- As outlined in the FASPM 2026 to 2029, a Framework Agreement Rebate is applicable to all patented or off-patented exclusive biologic drugs, and patented or off-patented exclusive drugs subject to Clause 10 of the FASPM 2026 to 2029.

- There are two Framework Agreement rebates applicable, based on when a drug was added to the Reimbursement List or priced as a hospital medicine; prior to 2026 (herein, "pre-2026"), or after 2026 ("herein, post-2026").
- The FASPM 2026 to 2029 should be referenced to identify which drugs are subject to the pre-2026 Framework Agreement rebate, and which drugs are subject to a post-2026 Framework Agreement rebate as references below in Table 1).

Table 1: Rebates on Sales

Year	Applicable timeframe	Rebate
Framework Rebate on New Medicines (post-2026) [a,b]		
1	1st of January 2026 to 31st of December 2026	9%
2	1st of January 2027 to 31st of December 2027	7%
3	1st of January 2028 to 31st of December 2028	6%
4	1st of January 2029 to 31st of December 2029	5%
Framework Rebate on medicines (pre-2026)[c]		
-	Patented or off-Patent Exclusive medicines approved for reimbursement on or before 31 December 2025	9%

Source: The FASPM 2026 to 2029

a As specified in the FASPM 2026 to 2029, "each Supplier shall rebate to the HSE: [X]% of the value (i.e. the relevant rebate for that year, as specified in Table 1), at the Price or relevant ex-factory price for on patent new medicines added to the Reimbursement List or a New Medicine priced as a Hospital Medicine between 1st of January 2026 to 31st December 2029" (i.e. post-2026).

b A "new medicine" is defined as "Medicine(s) with a Marketing Authorisation introduced in the State after the commencement of [the FASPM 2026 to 2029] during the Term, in respect of which a Supplier submits an application to the HSE pursuant to section 18 of the 2013 Act requesting their addition to the Reimbursement List or in respect of which a Supplier makes an application to the HSE to have it/them priced as a Hospital Medicine".

c For medicines that are not considered as "New Medicines", "Each Supplier shall rebate to the HSE 9% of the value, at the Price or relevant ex-factory price, for new medicines including new presentations and indications added to the Reimbursement List or a New Medicine priced as a Hospital Medicine prior to 1st of January 2026", (i.e. pre-2026).

- In addition, a scenario analysis should be provided whereby the 2029 Framework Agreement rebate (5%) is applied to all drugs for which the post-2026 Framework Rebate is applicable.

Duration of treatment

- Costs should be applied in the year that they are incurred (i.e. all costs for a 15-month treatment course should not be applied in Year One; instead the costs for 12

months of treatment should be applied in Year One, with the remaining three months of treatment applied in Year Two).

- For continuous treatments, partial calendar years are not acceptable in BIAs due to uncertainty in the exact date or month of introduction to the market.
- The duration of treatment should reflect expected real-world clinical practice;
    - Different considerations are required for interventions intended for long-term, continuous use as opposed to a discrete duration (e.g. until disease progression or unacceptable toxicity) or a defined treatment course (e.g. specified number of cycles) based on the product licence.
    - In line with data inputs for the CEM, estimates of time on treatment (ToT) for interventions expected to continue for a discrete duration should be based on the mean treatment duration observed in the relevant trial(s). This duration may be very uncertain if clinical trial data is immature i.e. a substantial proportion of the population are still receiving the intervention by the end of follow-up.
    - If data is immature, it is likely that the mean treatment duration for the trial population will be underestimated. In such cases, the most plausible prediction of treatment duration should be the estimated mean from the area under the extrapolated ToT curves in the CEM. Requirements for extrapolation of trial data are outlined in the Applicant Template. An alternative approach, if an exponential distribution can be assumed for ToT, is to calculate the mean duration directly from the median duration (median/ln(2)).

3. Drug Acquisition Costs (PAS)

Drug Acquisition Costs inclusive of a commercial in confidence (CIC) Patient Access Scheme (PAS) reflect the total drug cost to the HSE, inclusive of;

- Price to Wholesaler
- Wholesale mark-up
- Total rebate (Framework Agreement rebate plus CIC PAS)
- Value-added Tax

- Pharmacy fees (if applicable)

Please note: The majority of proposed CIC PAS are discounts on the price to wholesaler. This guidance describes the interpretation of such discounts by the NCPE and is not intended to dictate the structure of confidential discounts proposed by Applicants. Where an alternative discount structure is proposed, please contact bim@ncpe.ie.

The exact structure of the proposed CIC PAS should be clearly outlined.

- All estimates based on a CIC PAS should be presented as a scenario analysis, and highlighted as CIC in the Applicant Template. Estimates based on a CIC PAS should not be considered in the Applicant's base-case analysis.

Calculation of the PAS

Where a CIC PAS takes the form of a rebate to the price to wholesaler or other discount:

- The magnitude of wholesale mark-up does not change with the inclusion of a CIC PAS; therefore, wholesale mark-up should continue to be calculated based on the price to wholesaler.
- The magnitude of VAT does not change with the inclusion of a CIC PAS; therefore, VAT should continue to be calculated on the reimbursed price.
- The magnitude of the Framework Agreement rebate does not change with the inclusion of a CIC PAS. However, in many instances, Applicants incorporate the Framework Agreement rebate into the CIC PAS offering. It should be clearly documented in any proposed PAS whether discounts offered include or exclude the Framework Agreement rebate.
- The Applicant should specify whether the CIC PAS discount remains constant each year.
- Table 1 below provides an example of a parenteral drug, stored at room temperature, reimbursed under the CDS scheme (cost without PAS). The total CIC PAS assumed is 50.5%, inclusive of the Framework Agreement rebate (cost with PAS).

Table 2: Calculation of CIC PAS net costs a

Parameter		Adjustment	Cost without PAS	Cost with PAS
A	Price to wholesaler (PtW)		€1,000.00	€1,000.00

B	Wholesaler Mark-up	A *8%	€80.00	€80.00
C	Reimbursement price	A + B	€1,080.00	€1,080.00
D	Total rebate (Framework Agreement rebate + CIC PAS[c])	A * (-9% + -41.5%[c])	-€90.00	-€505.00
E	Net Price (PtW less total rebate)	A - D	€910.00	€495.00
F	VAT on Reimbursement Price	C * 23%	€248.40	€248.40
G	Total Drug Cost to the HSE per pack excluding VAT	C+D	€990.00	€575.00
H	Total Drug Cost to the HSE per pack including VAT	C+D+F	€1,238.40	€823.40

CIC: commercial in confidence; **HSE:** Health Service Executive; **NA:** not applicable; **PAS:** patient access scheme; **PtW:** price to wholesaler
[a] This example assumes an application has been made for reimbursement of a parenteral drug, required to be stored at room temperature, on the Community Drugs Scheme.
[b] Refer to NCPE Guidelines for inclusion of drug costs for information on mark-up and fees
[c] If applicable to the column.

4. Additional Costs and Cost-Offsets

Additional costs and cost-offsets which may impact the net healthcare budget impact, other than drug costs should be presented.

- Changes in healthcare resource utilisation may arise due to differences in route of administration, frequency and type of monitoring, adverse events, etc between the intervention and comparator(s).
- If the cost of a specific companion diagnostic test was included in the CEM, it should also be considered in the BIM by means of an average test-cost per patient in the intervention arm. In doing so, the Applicant should account for the proportions of the tested population with a positive and negative result, as per the methods described in the NCPE Applicant Template. The costs of the companion diagnostic should be assumed to be borne by the HSE in the base-case. If the Applicant proposes to incur the costs of the diagnostic test, this may be included as a scenario analysis. However, the likelihood of this arrangement persisting in the long-term should be considered.
- It is beyond the scope of the Rapid Review process to appraise the impact of an intervention on net healthcare budget impact; it is not required for Rapid Review submissions.

5. Results

- The results should be copied and pasted directly from the NCPE BIM Template into the Applicant Submission.

Scenario analysis

- A scenario analysis should be provided whereby the Framework Agreement rebate applicable to the year 2029 (5%) is applied to all drugs for which the post-2026 Framework Rebate, as outlined in the FASPM 2026 to 2029 agreement, is applicable.
- Results based on a CIC PAS may be presented as a scenario analysis only.
- The Applicant may present alternative scenarios (e.g. based on alternative market share values, or assuming that the treated population represents a subpopulation of the full licensed therapeutic indication). The methods used to implement the scenario in the BIM should be clearly described by the Applicant.

Appendix 1: Technical Specification Summary

This appendix is intended to provide guidance on how to use the NCPE BIM Template. Please note that this guidance is subject to updates, in line with the most recent version of the NCPE BIM Template.

General instructions

Cells highlighted in ORANGE are input cells for the Applicant in the form of a drop down menu
Cells highlighted in BLUE are input cells for the Applicant
Cells highlighted in YELLOW contain confidential information
Model check: Cells highlighted in PINK indicate missing information from Applicant.
Model check: Cells highlighted in GREEN indicate that all required fields have been completed.

- The NCPE BIM Template should be completed in sequential order, as inputs from the previous sheets may be required for subsequent calculations. Please ensure that all fields highlighted in blue and orange are completed before progressing to the next sheet.
- Worksheets in the NCPE BIM can be selected from along the bottom of the Excel file, or by using one of the buttons on the top-right corner of each tab throughout the template.
- Please ensure that all cells are appropriately linked to enable validation by the Review Group. Failure to do so may lead to delays in the appraisal process.
- The completed BIM should be fully modifiable.
- Please adhere to the official NCPE BIM Template and 'Guidelines for Inclusion of Drug Costs in Pharmacoeconomic Evaluations' for all calculations. Extra worksheets may be added for any additional explanations or calculations required to estimate parameter inputs. These should adhere to the flow of the BIM template, to enable validation, and to allow for scenario analysis by the Review Group.
- If the information you have for your BIM does not fit within the requirements of the template, please contact bim@ncpe.ie for advice.
- Each sheet should be completed in line with the guidelines provided in Sections 1 to 10 below.

1. **Title Page**

The purpose of the **title page** is to describe the intervention and comparators to be considered in the BIM.

- Please specify the number of comparators in Cell K39. This cell feeds into a macro which will hide all unnecessary comparator fields in the BIM. Please note where this field is incomplete, errors will occur in the BIM.

2. **Version Control**

The purpose of the **Version Control** sheet is to provide Applicants with information on changes made between versions of the BIM

- This sheet is for informative purposes only. No action is required by the Applicant.

3. **Irish Population Estimates**

The purpose of the Irish Population Estimates worksheet is to provide the background demographic estimates of the Irish population, to aid in identifying the population subject to the indication under assessment.

- Data on the Irish Population Estimates is routinely updated using data from the CSO, which is considered to be a high-quality reference.
- If using these estimates, it is important to show what population was used by highlighting the appropriate cells. The sum of the total population, the subpopulation who are at least 12 years old, and the subpopulation who are at least 18 years old, are provided in Rows 125 to 127. Where an alternative age range is required, please input this in Row 128.

4. **Patient Population**

The purpose of the Patient Population sheet is to describe how the treated population over the next five years is calculated.

Table 1: Eligible patient population

- Applicants should adhere to the BIM template, to increase transparency in patient number estimates and to permit scenario analysis by the Review Group.
- Please ensure that all cells highlighted in blue are completed. Fields in white will be

automatically populated.

- All calculations should be supported by an appropriate reference. The indicator cells will turn green once all references have been specified.
- The **prevalent** and **incident** patients may be calculated using estimates linked in from the "Irish Population Estimates" tab. Alternatively, the prevalent and incident cells can be manually inserted.
- In row 31 - Insert the **mortality rate** as a percent per annum of the patient cohort with the condition. If the mortality rate is not known or is minor, please set to 0.
- In row 33 - Insert the percentage of **patients eligible for the new intervention under the full licensed therapeutic indication.** In the absence of an appropriate justification for patient eligibility, please set to 100%.
- In row 35 – This proportion should account for any cases in which the eligible population is reduced as a result of patient factors, capacity constraints, etc. The Applicant must provide substantive evidence, in the submission dossier, for any such reductions. In the absence of an appropriate justification, this proportion should be set to 100%. This reduction may be removed by the Review Group, where it is deemed inappropriate.
  - In exceptional circumstances, wherein a subpopulation of the full licensed therapeutic indication is deemed appropriate, this may be accounted for in this proportion, as a scenario analysis. This restriction will be removed by the Review Group, where it is deemed inappropriate. Where a scenario analysis is required, the Applicant must submit a separate 'scenario analysis' BIM.

Table 2: Market share without intervention

- Estimated market shares must sum to 100% each year. A "check" is included in row 62 to remind the Applicant if this does not sum to 100%. This will change from red to green once the market share is equal to 100%.
- Additional information regarding how market shares were obtained, e.g. market research, can be submitted as a separate document/sheet/excel file. Cell J46 contains a reminder to complete the sources in Column J in the Table. This will change from red to green once the sources are completed.

Table 3: Market share with intervention

- Estimated market shares must sum to 100% each year. A “check” is included in row 82 to remind the Applicant if this does not sum to 100%. This will change from red to green once the market share is equal to 100%.
- Additional information regarding how market shares were obtained, e.g. market research, can be submitted as a separate worksheet. Cell J65 contains a reminder to complete the sources in Column J in the Table. This will change from red to green once the sources are completed.

Table 4: Discontinuation rates

- Use of a discontinuation rate is optional. The discontinuation rate may be used to limit the duration of treatment of a continuous intervention.
- For drugs calculated based on mean number of cycles, this will already take into account discontinuation rates. It is not appropriate to use both methods.
- Cell J85 contains a reminder to complete the sources in Column J in the Table. This will change from red to green once the sources are completed.

Table 5: Summary of population without new intervention

- This table is auto-populated (coloured white) and should not be modified.

Table 6: Summary of population with new intervention

- This table is auto-populated (coloured white) and should not be modified.

5. Drug Acquisition Costs

This worksheet calculates the price of the new intervention and any relevant comparators. The drug cost is inclusive of fees, rebates, and VAT if applicable. The price should correspond to the Price Application Form submitted to the HSE CPU, or HSE Primary Care Reimbursement Service file.

Scenario switch

- To apply this scenario, please select “Yes” in Cell F24 of the “Drug Acquisition Costs” sheet.
- As described on page 9, a scenario whereby a Framework Agreement rebate of 5% is applied should be provided.
- This scenario is implemented in the BIM as a 5% Framework Agreement rebate to all medicinal products indicated as a “Patented or Off-Patent Exclusive (post-2026)” or “Patented Exclusive or Off-Patent Exclusive and subject to clause 10 of Framework Agreement (post-2026)” in Table A.

Table 1a and 1b

- Tables 1a and 1b details the price of the intervention and comparator applied in each year of the BIM.
- Figures will automatically populate in Tables 1a and 1b based on selections in each respective Table G.
    - An exception to this is where "Manual input by Applicant" is selected in Table G. This will result in a blue coloured box in both Tables 1a and 1b. Please manually overwrite the formula with the appropriate figure. Please note that once this code is overwritten, the cell will no longer auto-populate based on selections made in Table G.

Please repeat the following tables (A to G) for the intervention and each comparator.

Table A

- Please input all information requested in Table A. Leaving cells blank can lead to errors in the formula, which can lead to unnecessary delays in the appraisal process.
- Up to four different pack types can be accommodated in this table across columns F to I. If there are less than four packs, please leave the extra columns blank. If there are more than four products, please contact bim@ncpe.ie.
- To ensure that each Framework Agreement rebate is applied accurately, the Applicant must ensure that the correct options in Table A are selected. It is the

responsibility of the Applicant to check whether the correct Framework agreement rebates have been applied in the base-case analysis and the scenario.

- Information is to be entered as follows;

Item	Description
Pack identification	• Enter identifying information (e.g. strength, pack size) for each pack. For example; column F: Drug Name 40mgx28; column G: Drug Name 20mgx28.
Calculation Starting Point	• Choose the calculation starting point: o Price to Wholesaler (PtW) o Reimbursement Price. • PtW is listed on the PAF submitted to the HSE. Reimbursement price is listed on the PCRS website.
Price per pack	• Enter the relevant pack price. Please specify the source for each cost.
Drug Funding Arrangement	• Choose the funding arrangements. o CDS = Community Drug Schemes o HT = High Tech Drug Arrangements o Hosp = Hospital.
Fridge	• Fridge item status is only required for the CDS as wholesaler mark-up varies here.
Oral product (including inhalers)	• Required for calculation of VAT. Oral products (including inhalers) are not subject to VAT.
Biologic	• Required for Framework Agreement rebate calculation.
If Biologic =Yes: Select Biologic and Patent Exclusivity Status[a]	• This field is required to inform the Framework Agreement rebate calculation. o Biosimilar o Patented or Off-Patented exclusive (pre-2026) ▪ This will apply a Framework Agreement rebate of 9%. o Patented or Off-Patented exclusive (post-2026) ▪ This will apply the Framework Agreement rebate as specified in the FASPM 2026 to 2029 in place for the particular year that the BIM is published [b]. o Off Patent Non-Exclusive 12.5% Rebate incorporated into Price to Wholesaler o Off Patent Non-Exclusive 12.5% Rebate o N/A
If Biologic =No, select	• This field is required to inform the Framework Agreement rebate

Non Biologic Patent Status[a]	calculation. ○ If Biologic = Yes, select N/A. ○ If Biologic =No, select one of the following; ○ Patented Exclusive or Off Patent Exclusive and subject to clause 10 of Framework Agreement (pre-2026). ▪ This will apply a Framework Agreement rebate of 9%. ○ Patented Exclusive or Off Patent Exclusive and subject to clause 10 of Framework Agreement (post-2026). ▪ This will apply the Framework Agreement rebate as specified in the FASPM 2026 to 2029 in place for the particular year that the BIM is published [b]. ○ Off Patent Non-Exclusive or Generic. ▪ If selected, no Framework Agreement rebate will be applied.

CDS: Community Drug Schemes; **HT:** High Tech Drug Arrangements; **Hosp:** Hospital; **N/A:** not applicable; **PAF:** Pricing Application Form; **PCRS**: Primary Care Reimbursement Service; **PtW:** Price to Wholesaler; **VAT:** Value added tax.

a Please note that patent exclusivity should be detailed in one appropriate field only. Failure to do so will lead to errors in the BIM.

b Where the scenario switch is set to "Yes", this Framework Agreement rebate is updated to reflect the rebate applicable to 2029 as outlined in the FASPM 2026 to 2029 (5%), across all medicines subject to a post-2026 rebate.

Table B

- Please fill in the fields in blue with a number and select the duration from the drop-down menus in orange.
- Information is to be entered as follows;

Item	Description
Length of treatment Cycle	• Treatment cycle is the length of time between each dispensing of the drug. For example, many oral tablets have a treatment cycle of 28 days. If a drug is administered once every six months, it can be assumed that the drug will be dispensed once every six months and the treatment cycle is six months. If there is confusion over whether a drug is administered (and thus dispensed) once every four weeks or once every month, refer to the SPC. • Enter treatment cycle length in column F and select unit of measurement (Days/Months) in column H. For treatment cycles measured in weeks, convert the number of weeks to days (e.g. four weeks = 28 days). One month is considered as 30.4375 days in the BIM.

Pack Identification	• This will auto-populate based on information provided in Table A.
Number of packs per treatment cycle	• Enter the number of packs of each pack presentation required per treatment cycle. For example, if the treatment cycle is 28 days, and there are 14 days' supply in one pack, enter "2" into column F. • Where each patient requires multiple products every treatment cycle, enter the number of packs of each pack type into the relevant column. For example, where a patient requires 2 x Pack (F) and 1 x Pack (G) every 28-day treatment cycle, please enter 2 in column F and 1 in column G. • Alternatively, where only a single pack is required by a patient each cycle but multiple strengths are available, a weighted average can be calculated by entering the relevant weight for each pack in every column. Ensure weights sum to 1. Add details of how weights are derived in notes section.

SPC: Summary of product characteristics.

Table C

- This table auto-populates based on the information inserted above.
- The Applicant should validate this table using the information provided in the NCPE 'Guidelines for Inclusion of Drug Costs in Pharmacoeconomic Evaluations'. This table should be copied and pasted directly into Section 4 of the Rapid Review Template and to Section 5.4 of the full HTA Applicant Template.
- For combination regimens, including drugs that are applicable to different Framework Agreement rebates, dispensing schemes, and/or VAT, it may be necessary to manually overwrite formulae in Table C. Where this is required, please ensure that modified cells are highlighted to clearly indicate to the Review Group that a change has been applied. For example, where the intervention may consist of an intravenously administered therapy in combination with an oral therapy, the VAT may be removed from Cell G75 of the 'Drug Acquisitions' Costs Sheet, wherein this cell should be subsequently highlighted in green).

Table D

- This table auto-populates based on scheme and product information inputted above in Table A.
- This table is not applicable to hospital drugs
- Please do not alter the formula in Table D.

Table E

- This section can be omitted for hospital drugs.
- The NCPE drug cost guidelines may be consulted for more information on non-dispensed patient care fees (applicable to the HT scheme only)
- Please do not alter the formula in Table D.

Table F

- This table should auto-populate based on the information provided above.
- Information regarding the number of treatment cycles (Column G) or Total cost per unit time (Column I) may be inputted.
- Irrelevant columns may be left blank.

Table G

- This describes the calculation method. The appropriate regimen should be selected for each comparator in the drop-down menu. The regimen used will be coloured in green and will be populated in Tables 1a and 1b. Please note that the corresponding cells in the "Drug Acquisition Costs (PAS)" tab will not be coloured in green so as to preserve the yellow commercial in confidence formatting.
- Treatment duration options include:

Duration type	Description
Total cost per treatment cycle	This option should be selected where patients are expected to receive only one cycle per year.
Total cost per X number of cycles	This option may be selected where the Applicant applies a mean number of cycles per year or for a treatment that is given for a discrete time period. This must be inputted to Table F.
Total cost per year	This option may be selected where a continuous treatment duration is considered.
Total cost per unit time	This option may be selected for treatments provided for a discrete time period.
Manual input by Applicant	This option may be selected where the cost for the

	intervention is described in a linked excel sheet. **Please note**: Once data is overwritten in Table 1a, this switch will become non-functional

Notes

- The Applicant should provide any additional detail necessary to permit validation of drug cost calculations by the Review Group.
- Please note that where drug cost calculations are insufficiently described, the BIM will be returned to the Applicant for review, which will lead to delays in the appraisal process.

6. Drug Acquisition Costs (PAS)

- Please complete the relevant sections for the intervention only. All other fields are for NCPE-use only and should not be altered.
- Please input the total rebate (i.e Framework Agreement rebate plus additional confidential discount) in cell E45. It is the responsibility of the Applicant to ensure that the correct discount has been applied. This sheet will auto-populate based on information provided in the 'Drug Acquisition Costs' sheet.
- If the proposed PAS differs from the methods applied in the NCPE BIM Template, please contact bim@ncpe.ie.

7. Additional Costs and Cost-Offsets

- Inclusion of additional costs and cost offsets, which may impact the net healthcare budget, is optional for full HTA submissions.
- Please describe in detail how additional costs were estimated. Additional rows may be added to this sheet in order to describe how estimates were derived.
- Please note: it is beyond the scope of the Rapid Review process to appraise the impact of an intervention on net healthcare budgets; the net healthcare budget impact is not required for Rapid Review submissions.

8. Results

- This will auto-populate based on information provided in previous sheets.
- Do not alter the formulae. Where the Review Group have identified inappropriate manipulation of the formulae, the BIM will be returned to the Applicant for review.

9. Results (PAS)

- This will auto-populate based on information provided in previous sheets.
- Do not alter the formulae. Where the Review Group have identified inappropriate manipulation of the formulae, the BIM will be returned to the Applicant for review.

10. References

- Any additional references used in the BIM calculations may be added from Row 24.
- Do not modify definitions used for the drug cost calculator.

Appendix 2: NCPE Budget Impact Analysis Reference Case

Table 1: NCPE reference case for BIA

Parameter	Description
Perspective	The perspective should reflect the publicly-funded health and social care system in Ireland, that is the HSE.
Intervention	The intervention should describe the drug, or combination of drugs, for which reimbursement is sought.
Comparator	The comparator(s) should reflect the current standard of care in Ireland.
Time horizon	The time horizon should incorporate estimates for five full calendar years.
Population	The population should be defined based on the full licensed therapeutic indication.
Mortality	Use of a mortality rate is optional. A mortality rate should only be applied where this is supported by an appropriate reference.
Net healthcare budget impact	Accounts for additional costs/cost-offsets.
Discontinuations	Use of a discontinuation rate is optional. A discontinuation rate should only be applied if there is substantive evidence that patients will not complete a full year's treatment course.
Market Share	The base-case market share should consider currently available therapies only.
Costs	Drug budget impact estimates only consider drug acquisition costs.
Uncertainty	The Applicant may present sensitivity and scenario analyses to support the assessment.