

SMC Principles of Budget Impact Assessment

January 2025



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# Introduction

## 1.1 Background

SMC provides advice on the clinical and cost-effectiveness of all new medicines for NHSScotland. As part of the assessment process, submitting companies are required to provide an estimate of the potential budget impact of the new treatment relative to existing practice for planning and implementation purposes. This is provided through completion of a standardised [SMC budget impact template](https://scottishmedicines.org.uk/making-a-submission/) which is issued in confidence to NHS Boards for medicines accepted for use by SMC. Budget impact information is not taken into account in the SMC decision on whether or not to accept a medicine for use.

## 1.2 What is budget impact assessment?

* A budget impact assessment is an evaluation of the expected cost or saving that results from implementing SMC advice.
* The focus of the SMC budget impact template is to show whether the cost or saving associated with the introduction of the new medicine is expected to have a cash impact for NHS Boards in Scotland. A non-cash impact may also be relevant if, for example, there are administration capacity benefits that do not result in cash (money) being saved.

## 1.3 Purpose of this document

* The purpose of this document is:
* To provide guidance for submitting companies on the key principles that should be followed when completing the SMC budget impact template
* To ensure consistency across budget impact assessments
* This document should be read alongside other SMC guidance manuals, that can be accessed via [SMC’s Making a Submission page](https://www.scottishmedicines.org.uk/making-a-submission/) where you will also find the budget impact template.

# Budget impact principles and perspectives

## 2.1 Timeframes

SMC’s budget impact template covers a period of up to 3 financial years (April-March) from the point of launch. This means the calculations should cover the remainder of the current financial year followed by two full financial years to provide an estimate of the predicted ‘steady state’ budget impact and patient numbers.

## 2.2 General principles for assessing budget impact

### Using standard accounting principles

* Standard accounting principles are applied.
* These principles are similar to health economic principles used in the cost-effectiveness calculations underpinning SMC advice but there are some differences, such as the budget impact template considers the impact on the population of Scotland whereas the health economic analysis considers the impact on an individual.

### Only including direct consequences

* Only direct consequences of implementing individual SMC guidance are included. Direct consequences are the changes in practice that will result from implementation.
* Indirect consequences cannot be considered in the budget impact assessment. As an example, a person who has an intervention that prevents them from dying could later develop other diseases that are costly to treat. The person could develop any disease unrelated to the guidance recommendation for their original condition. This would be an indirect consequence.

### Only including what is in scope of SMC advice

* Budget impact only covers changes funded by the NHS Health and Social Care system. This includes the funding of services provided by the public, private, third party and charity sectors.
* Value added tax is included within a budget impact assessment when payable by the NHS (ie for medicines provided in secondary care). The option to include VAT is available in the budget impact template.
* Homecare service costs are included when payable by the NHS.
* Costs are not discounted over time.
* The main focus of the budget impact is the impact of the new treatment on the medicines budget.

### Matching time periods for costs and savings

* Costs and savings relate to the same time period, usually a financial year. Differences may arise if costs are incurred earlier on that will result in savings in the future. It is not acceptable to combine costs and savings to produce a ‘net’ cost or saving if time periods do not match.

### Providing detailed information

* The budget impact template identifies the resource impact for the remainder of the current financial year and each of the next two financial years.
* National estimates should be provided. For local estimates the template can be amended to capture the results at a local NHS board level.

### Quality

* Data used are accurate and credible and sources are referenced
* The best available datasets are used and supplemented with expert opinion

# Completing the budget impact template

## 3.1 Background

To complete the budget impact template, the submitting company should identify:

* the population affected by the SMC advice, which may be smaller than the patient population covered by the licensed indication if a positioning is being sought
* the predicted net treated patient numbers following implementation of the SMC advice, including predicted uptake rate and discontinuation rate over time
* the dose, unit cost, relative dose intensity and duration of treatment associated with the new medicine
* the dose and unit cost associated with the comparator medicine(s), which should reflect the comparator(s) included in the health economic evaluation
* the administration type and costs associated with the new medicine and comparator(s)

## 3.2 Population sources

Resident populations by health board are sourced from the latest population estimates from the National Records of Scotland (Year 2022).

## 3.3 Incidence and prevalence data

Incidence and prevalence measure different aspects of disease or care need in a population, although they are related. The incidence rate is the rate at which new events occur in a population. The prevalence of a condition is the number of people in a given group or population who are reported to have the condition at a given time.

It is important to understand the basis on which data on incidence and prevalence are gathered and presented.

Examples of incidence and prevalence types include:

* annual incidence–the number of people who will develop a disease or have a care need over the course of a year; this is the most common way of expressing incidence
* point prevalence–the burden of disease or care need in a population at a particular point in time; this is the most common way of expressing prevalence

Incidence or prevalence data may be used in budget impact estimates. For example:

* the prevalence of a chronic condition lasting many years may determine its budget impact, but
* the annual incidence would be more appropriate to calculate the impact of a technology used to treat, for example, newly diagnosed cancer.

Both prevalence and incidence data may need to be considered within a single budget impact template, so that the budget impact of different medicine types can be calculated accurately.

The budget impact template is based on the population of Scotland. However, NHS Boards can amend the template to their local population to estimate the local resource impact.

## 3.4 Data sources to establish current practice

Data used to establish current practice vary depending on the topic. In some cases, multiple sources may be needed.

Commonly used types of data and sources used to establish a baseline may include:

* [Personal Social Services Research Unit](http://www.pssru.ac.uk/)
* [National Services Scotland](https://www.nss.nhs.scot/)
* hospital data, such as [Hospital Episode Statistics](https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics)
* primary care data
* prescribing data

In some situations current activity may be particularly difficult to define. When this is the case, assumptions may be required which should be clearly explained and justified.

## 3.5 Data sources to establish future practice

Predicting future practice after implementing SMC advice is challenging. Predictions of future uptake should not rely on a single source, when possible.

Assumptions should be documented, fully referenced and checked with clinical experts.

Sources used for estimating future practice include:

* previous uptake of similar medicines
* information used to inform related economic models
* relevant clinical experts

## 3.6 Prices used in the budget impact template

For some medicines, the Patient Access Scheme Assessment Group (PASAG) and the company agree that if accepted by SMC the medicine will be made available to NHS Scotland with a discount or Patient Access Scheme (PAS). The size of the PAS discount is commercial in confidence. Any PASAG approved PAS for the submitting medicine should be used in the budget impact template, along with the list price, to allow both the with PAS and list price budget impact estimates to be calculated.

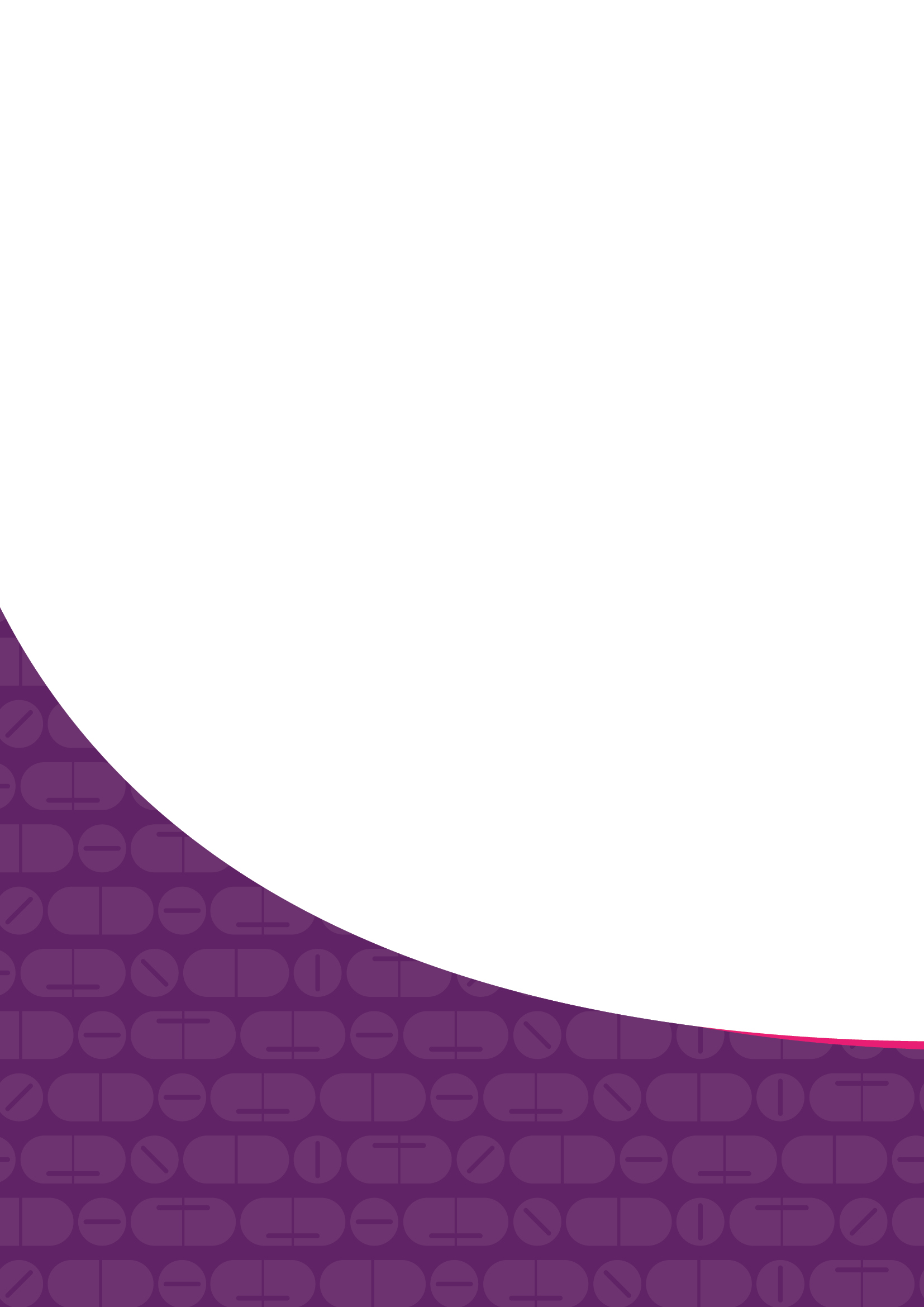
For comparator medicines available with a PAS, the list price should be used. However, the NHS Boards will have access to the confidential comparator PAS discount level to allow this to be factored into the overall budget impact estimates in confidence.

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