| | |
|---|---|
| **Title:** Accelerated Access Collaborative for health technologies<br><br>**IA No:** 13003<br>**Lead department or agency:**<br>Department of Health<br>**Other departments or agencies:**<br>Office for Life Sciences | DH Impact Assessment (IA)<br>**Date:** 04/09/2017<br>**Stage:** Final<br>**Source of intervention:** Domestic<br>**Type of measure:** other<br>**Contact for enquiries:** |

## Summary: Intervention and Scenarios

**RPC Opinion:** N/A

| Cost of Preferred (or more likely) Scenario | | | |
|---|---|---|---|
| **Total Net Present Value Range** | **Net cost to business per year** | **In scope of One-In, Two-Out?** | **Measure qualifies as** |
| -£4,266m to £7,278m | £ N/A | No | N/A |

**What is the problem under consideration? Why is government intervention necessary?**

When new technologies generate net patient benefits, any barrier to their use deprives patients in the NHS overall of health gains, and may reduce the wider societal impacts of improved patient health. Government intervention is required to reduce avoidable or unnecessary delays or barriers to the use of technologies which generate net patient benefits.

**What are the policy objectives and the intended effects?**

The primary objective is to reduce unnecessary delays or barriers to the use of slected technologies which generate greater net patient benefits - and thereby increase the overall benefits realised from the NHS budget. Additional intended benefits are: to reduce the costs to companies of gaining approval for their products; and to increase investment in UK R&D.

**What policy scenarios have been considered, including any alternatives to regulation?**

We have included policy implementation options to illustrate a broad possible range of outcomes including:

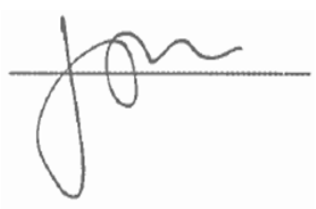
1. Low risk - accelerate use and uptake of technologies with a mature evidence base (med tech only). **Net present value = £7,278m**
2. Medium risk (intended policy) - accelerate use and uptake of technologies with a mature evidence base (med tech) and where companies will consider price reductions (medicines). **NPV = £3,283m to £5,057m**
3. High risk - accelerate use and uptake of medicines with immature evidence base. **NPV = -£4,266m to -£1,090m**

Given that the policy, as formulated, gives some flexibility to Ministers and AAC members, a range of options remain open

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date: 2020**

| | | | | | |
|---|---|---|---|---|---|
| Does implementation go beyond minimum EU requirements? | | | No | | |
| Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. | **Micro**<br>n/a | **< 20** | **Small** | **Medium** | **Large** |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:**<br>N/A | **Non-traded:**<br>N/A | |

***I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.***

Signed by the responsible Minister: Lord O'Shaughnessy  Date: 16/11/2017

# Summary: Analysis & Evidence

Scenario 1

**Description: Accelerated Access Collaborative (Lowest risk)**

| Price Base Year 2016 | PV Base Year 2016 | Time Period Years 5 | Net Benefit (Present Value (PV)) (£m) Best Estimate: £7,278m |
|---|---|---|---|

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| Low | | | | |
| High | | | | |
| Best Estimate | | | | £3,845m |

**Description and scale of key monetised costs by 'main affected groups'**

The main affected groups are patients. The £3,845m is the cost to those patients whose care is displaced by the new technologies. This amounts to 50,800 QALYs valued at £60,000 each. The change in the NHS budget is a net saving of £381m which is counted as a benefit below.

**Other key non-monetised costs by 'main affected groups'**

N/A

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| Low | | | | |
| High | | | | |
| Best Estimate | | | | £11,123m |

**Description and scale of key monetised benefits by 'main affected groups'**

The main affected groups are patients. The benefits are 152,000 QALYs valued at £60,000 each

**Other key non-monetised benefits by 'main affected groups'**

N/A

Key assumptions/sensitivities/risks — **Discount rate (%)** 1.5% NHS / 3.5% other

The key assumptions are that new medical technologies can deliver care at incremental cost effectiveness ratios of £10,000 per QALY (i.e. better than existing NHS care) and /or deliver large savings. If these assumptions are net of the options considered in this impact assessment, this option delivers the largest NPV at £7,278m.

**BUSINESS ASSESSMENT (Scenario 1)**

| Direct impact on business (Equivalent Annual) £m: | | | In scope of OITO? | Measure qualifies as |
|---|---|---|---|---|
| Costs: | Benefits: | Net: | No | |

## Summary: Analysis & Evidence

Scenario 2

**Description: Accelerated Access Collaborative (medium risk – most closely reflects intended policy)**

| Price Base Year 2016 | PV Base Year 2016 | Time Period Years 5 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | Low:£3,283m | High: 5,057m | Best Estimate: £4,453m |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| Low value | | | | £4,347m |
| High value | | | | £2,570m |
| Best Estimate | | | | £3,174m |

**Description and scale of key monetised costs by 'main affected groups'**

Patients are the main affected groups. Costs range from £2,570m to £4,347m depending on whether price reductions for medicines can be delivered and on the incremental cost effectiveness ratio of NHS care forgone. The main cost above is the value of 33,500 to 58,000 QALYs displaced. The budget implication for the selected medicines is a net increase of between £186m to £368m from running the AAC for 5 years. Finding the resource to fund them displaces the 33,500-58,000 QALYs. The net impact on the NHS budget of the portfolio of selected technologies is negligible because the med tech products are cost saving.

**Other key non-monetised costs by 'main affected groups'**

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| Low value | | | | £7,629m |
| High value | | | | £7,627m |
| Best Estimate | | | | £7,627m |

**Description and scale of key monetised benefits by 'main affected groups'**

The main affected groups are patients. They receive approximately 101,000 QALYs valued at £60,000 per QALY

**Other key non-monetised benefits by 'main affected groups'**

Key assumptions/sensitivities/risks **Discount rate (%)** 1.5% NHS / 3.5% other

This options shows a selected portfolio from a broad range of technologies with a mature evidence base. Compared to Scenario 1, substituting medicines for some of the medical technologies has reduced the net present value to £4,453m (central estimate). Without a price reduction, the two medicines selected deliver a net loss of £277m. This net loss would increase if medicines make up a higher proportion of the products selected by AAC – reducing the overall NPV. Price reductions of 8.6% to 9.7% would be required to break even. The ability of the NHS England Commercial Unit to deliver these price reductions is untested. Relaxing the assumption about the cost of the care displaced by introducing the medicines increases the NPV to £5,057m

**BUSINESS ASSESSMENT (Scenario 2)**

| Direct impact on business (Equivalent Annual) £m: | | | In scope of OITO? | Measure qualifies as |
|---|---|---|---|---|
| Costs: | Benefits: | Net: | No | |

# Summary: Analysis & Evidence

Scenario 3

**Description: Accelerated Access Collaborative (Highest risk)**

| Price Base Year 2016 | PV Base Year 2016 | Time Period Years 5 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | Low: | High:-£1,090m | Best Estimate: -£4,266m |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| Low value | | | | |
| High value | | | | £3,261m |
| Best Estimate | | | | £6,436m |

**Description and scale of key monetised costs by 'main affected groups'**

The main affected groups are patients. £6,436m falls to them and is the value of lost care. An extra £1,289m is required to pay for the selected medicines and is funded by displacing care from elsewhere in the NHS. Expressed relative to the NICE range of incremental cost-effectiveness ratios, if we assume that the care forgone is care with a ICER of £30,000 per QALY rather than the normally assumed £15,000 per QALY, the cost would be £3,261m.

**Other key non-monetised costs by 'main affected groups'**

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| Low value | | | | |
| High value | | | | £2,171m |
| Best Estimate | | | | £2,171m |

**Description and scale of key monetised benefits by 'main affected groups'**

The main affected groups are patients. The selected technologies deliver 29,000 QALYs valued at £60,000 each

**Other key non-monetised benefits by 'main affected groups'**

Key assumptions/sensitivities/risks — **Discount rate (%)** 1.5% NHS / 3.5% other

The risk with selecting medicines with an immature evidence base is that it is difficult to determine the health benefits to patients. There is a risk this creates an incentive for selective presentation of trial evidence (or missing evidence) that could inflate the apparent value of benefits to patients. This would lead to a higher final price for medicines than if the evidence base was allowed to be completed before a decision about pricing is made. The net loss could be £4,266m if 5 such medicines are selected. This reflects the value of care patients could have received instead if the money to fund these 5 medicines had been spent on other interventions.

**BUSINESS ASSESSMENT (Scenario 3)**

| Direct impact on business (Equivalent Annual) £m: | | | In scope of OITO? | Measure qualifies as |
|---|---|---|---|---|
| Costs: | Benefits: | Net: | No | |

# Problem

New approaches to treating patients or delivering services (hereafter referred to as "technologies") are continually being developed and made available to the NHS. New technologies may increase the patient benefits generated by the NHS overall, either:

- by providing greater health gain to patients than would be expected if the technology's net costs were used elsewhere in the NHS (i.e. the technology is "*cost-effective*"); or
- by enabling health gains to be delivered at lower overall cost - thereby releasing funds to provide additional benefits to patients elsewhere in the NHS (i.e. the technology is "*cost-saving*").

The adoption of new technologies by the NHS entails transition from a state in which the technology is not used at all, to a state in which it is used to the *fullest appropriate extent*.

The *fullest appropriate extent* may be considered to represent the use of the technology in all circumstances in which it increases (or does not decrease) the benefits realised by NHS patients overall – that is, in all circumstances in which it is cost-effective or cost-saving.

The general problem addressed by the proposals evaluated in this Impact Assessment is: there are unnecessary barriers to the adoption of technologies by the NHS to their fullest appropriate extent, including speed of uptake. Any avoidable impediment to the adoption of cost-effective or cost-saving technology deprives patients overall of benefits, and reduces the possible health of the UK population.

Addressing these barriers, and increasing the use and uptake of cost-effective and cost-saving technology, would increase the total benefits realised by NHS patients.

## Objective

The primary objective is to reduce unnecessary delays or barriers to the use of technologies which generate net patient benefits - and thereby increase the overall benefits realised from the NHS budget.

Additional intended benefits are: to reduce the costs to companies of gaining approval for their products; and to increase the investment in UK R&D, either directly or through increasing the attractiveness of the UK as a location for foreign investment in R&D.

This impact assessment focuses on the introduction of the **Accelerated Access Collaborative** (AAC) and the associated AA pathway ( AAP) and the impacts of the portfolio of products covered by the AAC.

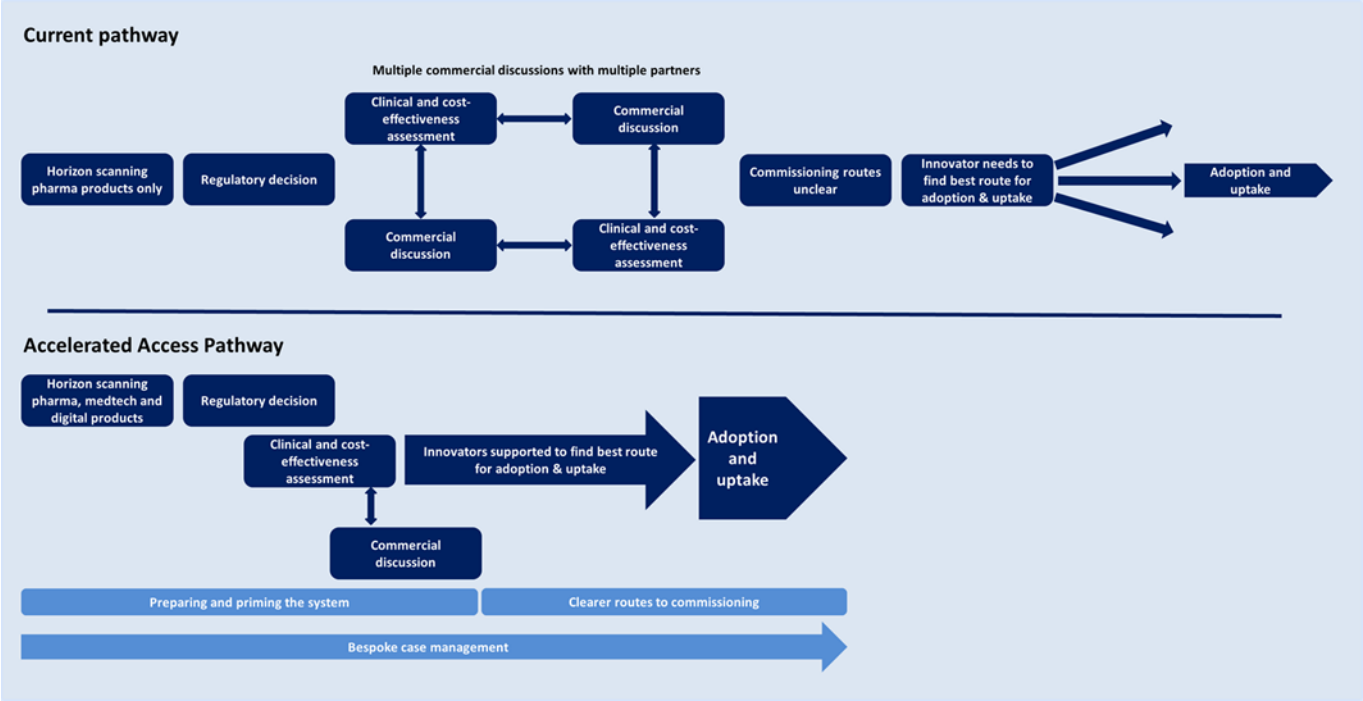
# Description of measures for evaluation

## Accelerated Access Collaborative (AAC) and Pathway

The Government's response to the accelerated access review commits to creating an accelerated access Collaborative that will have an independent chair and the aim to improve collaboration between Government, NHS England, NICE, NIHR, MHRA, NHS Improvement, AHSN and patient and industry voices. More specifically, the collaborative will:

- articulate areas of healthcare priorities to innovators
- horizon scan new technologies with the aim of identifying a subset of transformative products through the accelerated access pathway
- streamline the pathway from market authorisation through to patient use for transformative products
- co-ordinate across partners to provide case management for each transformative product

At present medical technology do not have a clearly defined pathway. The diagram below illustrates the routes for adoption and uptake and shows how the pathway may be modified to deliver faster access to new products for patients.




## Description of current pathway

Pharmaceuticals and medical technologies are evaluated by Medicines and Healthcare products Regulatory Agency (MHRA) / European Medicines Agency (EMA), and awarded Marketing Authorisation if they are considered safe and effective.

Subsequently, for medicines, companies make submissions to NICE providing evidence of the products' clinical effectiveness and (with price and other cost information) their cost-effectiveness. NICE appraisal committees, supported by independent expert reviewers, consider the company's submission and determine whether the product should be recommended for use in the NHS. The cost-effectiveness of each individual medicine varies (based on factors such as their clinical effectiveness, price, other related health system costs and savings). This impact assessment assumes that, on average, new medicines have an incremental cost-effectiveness ratio of £32,000 / QALY if used in the NHS (reflecting the standard cost-effectiveness threshold, end of life criteria and Highly Specialised Technologies process) . Medical technology products are more likely to be subject to NICE guidance rather than technology appraisals.

In respect of pharmaceuticals, a positive NICE recommendation is associated with a funding requirement – such that commissioners must fund the product if it is prescribed. The process of appraisal is usually completed 18 months following Marketing Authorisation.

## "Transformative" designation and qualification for the AAC

To be designated as transformative a technology must:

- demonstrate high potential to transform service delivery leading to substantial efficiency gains, net of product costs, and opportunities for reinvestment (e.g. £10m of realisable savings for the NHS)

OR

- demonstrate high potential for major improvement to patient-relevant outcomes (e.g. deliver a health gain to each patient of 2 QALYs)

In addition to satisfying one or both of the criteria above:

- The technology should be aligned with NHS priorities
- The company owning the technology should indicate agreement to engage in commercial negotiations to ensure availability to NHS patients in a financially sustainable way, with a commercial proposal that delivers additional benefit to the NHS commensurate to the benefits accrued from AAC support.
- The budgetary impact of the technology should be financially sustainable for the NHS. The AAC should also be mindful of the cumulative budget impact of all technologies supported by the AAC.
- AAC members are able to add value in speeding up the process of adoption and otherwise support access to a particular product on the NHS.

To be designated transformative on the basis of potential for service redesign and efficiency gains, the AAC would anticipate delivery of efficiency savings[1] across the NHS in England. Technologies offering high potential for such efficiency savings are more likely to be health prevention interventions, medical technologies or diagnostics rather than medicines. Medicines will be assessed by NICE using their standard methodology, and a positive appraisal will indicate that the medicine is recommended for use in the NHS. In many cases, delivery of the efficiency savings will be dependent on reengineering care pathways rather than on simply introducing the technology. The AAC will have a key role in encouraging and facilitating such care pathway reengineering to ensure maximal gains from technologies designated as transformative.

To be designated transformative on the basis of potential for major improvement to patient-relevant outcomes, the AAC would anticipate a significant individual patient benefit.[2] The AAC should also take into account benefit to a wider population, where this is not fully represented in the individual patient benefit assessment. Where the AAC has assisted in the accelerated patient access for a technology designated as transformative, it is expected that the NHS will benefit through commercial arrangements that acknowledge the AAC contribution as well as earlier market access and associated company revenues.

## Support for the adoption of Transformative products

Targeted funding will be made available to support innovation in the NHS and the adoption of the technologies selected by the AAC. It covers 4 areas:

- Funding to help SMEs and not-for-profit organisations participate in EAMS;
- Funding for SMEs developing digital or medical technologies to gather real world evidence of performance and cost-effectiveness. This would follow an EAMS-like approach;
- Additional baseline funding for AHSNs (of which there are 15) to increase their capacity and capability to support local assessment of technologies and knowledge exchange, and to promote the spread of innovation nationally through innovation exchanges; and
- Additional capacity and capability for AHSNs to undertake any necessary clinical changes following implementation of a new technology. This would be achieved through a Pathway Transformation Fund (PTF).

[1] Expected to be in the region of £10m for products with a budget impact of £25m as modelled in this IA

[2] To be determined but expected to be in the region of 2 QALYs

The funding will be £17m per year, of which £2m will support SMEs (EAMS and med tech) with the remainder going to AHSNs.

### Price negotiation

- Prior to NICE appraisal, the company and the NHS are expected to conduct a negotiation to agree a price for the product. This is important for medicines which are selected because without a price reduction acceleration of market access through the AAP will add considerably to costs..

### NICE appraisal

- NICE appraisal will be carried in parallel with the marketing authorisation process and a decision given as soon as possible after the product has received marketing authorisation.
- The process of NICE appraisal will be modified for AAC products, to enable an additional outcome: recommendation for conditional approval, where applicable.

### Early Access to Medicines Scheme (EAMS) – *pharmaceuticals only*

- After selection for the AAC, pharmaceutical products may enter an Early Access to Medicines Scheme (EAMS), if appropriate. This scheme begins before the product's marketing authorisation, and is expected to last for 9-12 months.
- Entering EAMS is not a requirement for a product to be considered for the remainder of the AAC – and products can join the pathway at any point.

### Conditional approval period for managed access

- Products receiving conditional approval will be funded according to the commercial agreement between the company and NHS England.
- Companies whose products receive conditional approval will be required to conduct data collection exercises
- After a period of 2 years of conditional approval, the product will again be considered by NICE to determine if it should receive approval for baseline funding in the NHS. This decision will use the data collected during the conditional approval period alongside randomised control trail results. The standard of evidence will be at least as rigorous as that used for the standard approval process.

# Accelerated Access Collaborative: Discussion of the assumptions and risks

## Assumptions

There are a number of significant risks to delivering a strongly positive net present value. 3 assumptions have the most impact on the value for money of the policy proposal. These are:

- The basket of technologies selected by AAC
- The cost effectiveness of NHS care foregone to fund the AAC selected technologies
- The level of certainty of the health benefit of each AAC selected technology

## Basket of products

The modelling of this impact assessment has categorised the technologies into one of five theoretical groups to illustrate different characteristics of technology that may be considered for the Accelerated Access Pathway :

- Medical technology products (cost effective) – products that cost the same but deliver health at an improved rate compared to the NHS average, i.e. deliver QALYs at £10,000 per QALY compared to the average £15,000 per QALY for typical NHS spend
- Medical technology products (cost saving) – i.e. products that deliver the same health gain but are cost saving, e.g. deliver savings elsewhere in the NHS
- Medicines (accelerated access) – pharmaceutical products which would previously have had an incremental cost effectiveness ratio (ICER) within the NICE upper range but where NICE approval is accelerated to be at or as soon after marketing authorisation as possible
- Medicines (EAMS) – pharmaceutical products which may enter the Early Access to Medicines Scheme, if applicable, and would be available to patients at least 9 months prior to market authorisation
- Medicines (managed access) – pharmaceutical products that have an immature evidence base and receive a conditional period of managed access

A **cost effective medical technology device** is assumed to require the same level of expenditure as existing technologies but deliver more health gain for that expenditure. On average, the model assumes that care is delivered at a rate of 1 QALY for £10k of expenditure[3]. **Cost saving devices** deliver the same amount of benefit to patients as existing technologies but are either less expensive or deliver savings to the NHS at other points along the care pathway[4]. The released resources become available to deliver additional care to patients at the average rate of health gain from NHS care (see cost effectiveness of care foregone below). Therefore, adopting these technologies and, indeed, speeding up their adoption is clearly desirable.

Under current arrangements innovative medicines are subject to appraisals by NICE to determine their cost effectiveness. The impact assessment modelling assumes pharmaceutical companies set their prices to maximise their revenues[5] and that the cost per QALY is higher than the typical rate at which the NHS as a whole delivers care (at the margin). Medicines may also generate efficiencies elsewhere in

[3] At present NICE does not conduct routine HTA for all medical technologies. Discussion with NICE colleagues suggest ICER of £10k/QALY for medical technologies to be realistic

[4] Systematic HTA evidence is not available. Discussion with NICE suggest savings can be delivered with examples up to 200% of cost of original product

[5] i.e. just below the upper range at which NICE will grant approval given the health gain of the medicines

the care pathway. However, unlike for medical technology products, the NICE process allows pharmaceutical to capture that value in the price of the medicine.

All the medicine categories illustrated here share these characteristics. **Medicines (accelerated access)** means they are adopted earlier, i.e. at or as soon after market authorisation as possible

**Medicines (EAMS)** have the additional characteristic that they are made available to patients ahead of marketing authorisation where completed. EAMS has been targeted at medical conditions where there is substantial unmet patient need. Pharmaceutical companies do this without charging for the use of the medicine. Use of medicines without charge offers good value for money and reduces the size of the lost value from simply speeding up access.

**Medicines (managed access)** are medicines with an immature evidence base. This makes it difficult to assess the size of the health gain to patients, which in turn makes it difficult to set a price at a cost effective level. Offering NICE conditional approval with managed access could lead to higher final prices compared to waiting for a mature evidence base before setting prices. (See *level of uncertainty* section below).

Note that the categories listed here are indicative for the purposes of building the scenarios in the impact assessment. In practice, individual medicines may display characteristics more akin to the "medical technologies" categories here and vice versa.

## Cost effectiveness of NHS care foregone

This impact assessment uses the central assumption that the NHS as a whole generates additional health gain for patients at the rate of 1 Quality Adjusted Life Year (QALY) for every additional £15,000 spent. This is standard for Department of Health impact assessments and is based on research at the Centre of Health Economics York by Karl Claxton et al[6]. This assumption is used to estimate the opportunity cost of spending NHS resources on the policy proposal (in this case the technologies selected by the AAC). If a policy leads to more health gain being generated for the same level of resource (or the same level of health gain for less money) then it is cost effective. The reverse is also true. The actual health foregone will depend on the treatment foregone to fund the policy. This cannot be known, so the average from the Claxton research is chosen.

This impact assessment also includes sensitivity analysis that considers an alternative cost effectiveness for care foregone of £30k/QALY, in order to illustrate the impact in the context of NICE's range of acceptable ICERs.

## Level of certainty of the health benefit

As mentioned above in the discussion on the basket of products under consideration for AAC, the standard NICE approval process assesses the benefits of the new medicine. This is done through a health technology appraisal (HTA). This process will not change for the accelerated medicines. It does have an implication for the medicine (managed access) category of technology, where a conditional approval for use would be given even though the evidence base on the health value of the technology is immature.

If the benefits are not known, it is difficult to ascertain whether the proposed price offers value for money. In the medium term, once the price has been set, if the benefits turn out to be lower than expected then a medicine at the initially agreed price is likely to offer poor value for money.

6 https://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP81_methods_estimation_NICE_costeffectiveness_threshold_(Nov2013).pdf

Normal approval by NICE requires that the most plausible cost per QALY estimate for a new product should be within the relevant acceptable ICER range. As the level of QALY gain is an estimate with a confidence interval around it, the true level of health gain is uncertain.

The next section sets out how this uncertainty presents a risk of the NHS paying higher prices and why once a medicine is in use it may be difficult to negotiate a lower price or to withdraw from using the medicine.

## Risk

There are a number of notable risks and the comprehensive management and mitigation of these during the implementation phase is essential to the Accelerated Access Collaborative delivering an overall benefit.

The scenario in which products can be recommended for conditional approval with an immature evidence base means uncertainty around the true level of health gain is likely to increase. In turn, higher uncertainty may lead to a higher implicit ICER. Once new medicines have been commissioned, they are difficult to decommission and there is a risk they will enter mainstream commissioning at ICERs greater than would normally be the case.

There may also be an incentive for companies to position strategically their submissions to show greater levels of uncertainty. Consider the following example: NICE may not ordinarily approve a medicine with a plausible ICER of £40,000 +/- £10,000. However, for the conditional approval pathway, it is possible that the AAC may consider a medicines with a plausible ICER of £40,000 +/- £20,000. As a result, there would be a risk of introducing a disincentive for companies to provide good evidence.

For modelling purposes in this impact assessment, the marginal health gain associated with the ICER accounts for half the value of the gross price for a medicine. If the increase in uncertainty leads to an unintended increase in the ICER of 50%, then the assumed increase in the gross price is 25%.

### *Moving from conditional approval to baseline commissioning*

It is proposed that products will be assessed after the 2 year period of conditional approval, based on data collected during that period, before a decision is made on moving the product to baseline commissioning.

In principle, this assessment should provide a checkpoint at which spending at these prices could be prevented from moving into baseline commissioning – either by discontinuing approval for the product, or by compelling the company to provide it at a lower, cost-effective price.

### *Effect of lower initial evidence requirements on list price*

Entry into managed access only requires that the confidence interval of the cost per QALY estimates contains the upper end of NICE's normal range. This means that companies could set a higher initial or list price, and still qualify for managed access. This initial price may also affect the price for baseline commissioning, insofar as companies may use it as the starting point for price negotiations.

### *Over-estimation of clinical effectiveness*

A lower up front requirement for evidence to get conditional approval means the NHS is likely to over-estimate the clinical effectiveness of products. This can occur for two reasons: first, by selecting only the most promising products with the highest estimated health gains for the AAR, it becomes statistically more likely that the true clinical effectiveness is lower than initial data suggests (this phenomenon may be referred to as *'regression to the mean'*[7]). Second, there is a risk that companies

[7] Very promising clinical trial results can occur due to two reasons – a. the product is truly very cost effective and b. the result was a fluke. The greater the number of clinical trials conducted on a product, the easier it will be to tell the difference between the truly promising and those that just got lucky in the beginning. When less data is available, we would expect that the products we have selected due to their promising nature to

could select or withhold data in order to increase the QALYs claimed[8]. This would enable prices to be set above the cost-effective level in the managed access period.

### *Insufficiency of "real world" evidence to support negotiation of a cost-effective price*

Following managed access some conditional approval medicines may not have delivered the hoped for level of health gain. The ability of NHS England to negotiate commensurately lower price, or to withdraw funding from a drug that is not as effective as originally assumed will, in part, depend on the evidence collected during conditional approval. It is important to note that measuring clinical effectiveness (and therefore cost-effectiveness) requires properly-designed clinical trials which compare outcomes for patients receiving the drug with a matched control group who do not. Without such a control group it is difficult to determine whether any health effect is attributable to the drug. Therefore the use of health technology assessments will remain the foundation of the NICE process.

### *Pressure not to withdraw a product already in use*

In negotiating a price for baseline commissioning after the managed access period, NHS England may be disadvantaged by the fact that **the product is already in routine NHS use** – and it may be politically difficult to withdraw funding.

## Effects on product prices

The proposed changes to appraisal of medicines, and the introduction of conditional approval for medicines, could change the effective prices paid by the NHS for drugs. The consequences of different price outcomes are very large changes in the magnitude as well as the nature of impacts.

### *Risks that the NHS will not achieve price reductions*

In order to achieve value for money, the scheme needs to have the technologies that are selected to deliver significant efficiencies elsewhere in the NHS. If the new system also enables the NHS to get better deals, and lower prices for drugs, this could result in even greater cost-savings.

However, if efficiencies are not forthcoming, accelerated access would not be a cost neutral policy. Technologies would need to deliver lower prices over their lifetime to release the resource to pay for their use in the accelerated access period. Price reductions required to achieve "break even" in respect to NHS costs imply companies accepting prices corresponding to an ICER of under £20,000 / QALY.

### *Risks that companies will be able to achieve price increases*

As described above, products may qualify for conditional approval if the confidence interval of cost-effectiveness estimates includes the relevant normal NICE range. All else being equal, this enables companies to increase the prices at which they can gain conditional approval..

Additionally, the system may risk creating incentives for companies to restrict and/or select the evidence they provide to NICE, in order to widen the range of cost-effectiveness estimates and enable conditional approval at a still higher price.

Depending on how the system is implemented, this change to evidence requirements risks leading to large price increases. As shown above, the outcomes for NHS spending and net impacts are extremely sensitive to price effects.

### *Risks that products gaining conditional approval will move to baseline commissioning at high prices*

include a mixture of both types of products, and so, on average, we would expect the true clinical effectiveness to be lower than was initially estimated.

[8] For an illustration of how selective reporting of trials can lead to increased estimates of health benefit, see the example of *Tamiflu* (link).

As described above, there may be a risk that the system permits companies to gain conditional approval at higher prices than would be commensurate with normal approval. In principle, these prices will only persist for the duration of the conditional approval stage of the process – 2 years.

The mechanism by which products are assessed at the end of the conditional approval phase is not yet defined. The proposal entails collection of evidence from use of the product during the conditional period. However there is a risk that the evidence will not be sufficient to prove whether a product is cost-effective or not, as it will not be collected as part of a controlled trial.

Overall there may be a risk that the NHS will be required to prove that a product is not cost-effective, in order for it to be prevented from moving to baseline commissioning – but that the evidence to conclusively demonstrate cost-effectiveness (or the lack thereof) will not be available.

# Accelerated Access Collaborative: Analysis of Costs and Benefits

## Overview of effects and ultimate impacts

This sections sets out the impacts of implementing the AAC. The AAC can select 5 technologies per year and Ministers have discretion to direct the AAC towards the type of technologies that they should focus on. The actual portfolio selected by the AAC will depend on that remit, the technologies available for selection each year and the views of the AAC participants on the priorities of the NHS.

Three implementation scenarios are presented here which are illustrative of the selection range open to the AAC. The AAC is not restricted to choosing one of these exact scenarios. The scenarios are categorised at one end by low risk technologies where the evidence of the benefits is known, making them straightforward to price, through to high risk technologies where the benefits are unclear, making them difficult to price.

The 3 scenarios, drawn from different combinations of products as defined in the "Basket of Products" section, are:

- Scenario 1: Accelerated Access Collaborative selects medical technologies with mature evidence base (lowest risk)
- Scenario 2: Accelerated Access Collaborative selects medical technologies and medicines with mature evidence base (medium risk)
- Scenario 3: Accelerated Access Collaborative selects 5 medicines with immature evidence base (highest risk)

The policy intention is that the AAC will select a portfolio of products broadly in line with Scenario 2. This is a balanced range of products including medicines and medical technology products.

#### *Sensitivity analysis within the scenarios*

Where appropriate, sensitivity analysis is used to show the impact on value for money of relaxing the cost per QALY counterfactual from £15,000/QLAY to £30,000/QALY, to consider the implications relative to NICE's range of acceptable ICERs. This is relevant to medicines and therefore applies to scenarios 2 and 3.

Scenarios 2 and 3 also look at the effects of price reductions to the medicines. This increases the level of net benefits because the lower expenditure on the new medicines which results from the reduced price means less care is displaced from other parts of the NHS to pay for them than would otherwise be the case.

### Summary of results

The table below shows the net benefits for the scenarios modelled. Low, mid and high value estimates are generated, where appropriate, by incorporating the sensitivities described above: varying the assumptions about the effective increment cost effectiveness ratio (ICER) for the medicines and NHS care being displaced to pay for the AAC portfolio.

| | Net Benefit Range | | |
|---|---|---|---|
| | Low value estimate | Mid value estimate | High value estimate |
| Scenario 1 | n/a | £7,278m | n/a |

| | | | |
|---|---|---|---|
| (low risk) | | | |
| Scenario 2 (medium risk) | £3,283m | £4,453m | £5,057m |
| Scenario 3 (high risk) | n/a | -£4,266m | -£1,090m |

The selection of the basket of technologies by the AAC have a big impact on the net present value of the policy. Scenario 1 has the highest net benefit over the 20-year modelling period (£7,278m) because it selects technologies with a high degree of certainty about their health value (and so can be priced accordingly) and where the expected ICER is at or below than the typical marginal value for existing NHS care. As more risk is taken by introducing medicines with either an immature evidence base or expected ICER higher than the typical marginal value for existing care, then the net benefit falls.

Scenario 2 includes some medicines in the selection. Without price reductions the 2 medicines selected have a combined net loss of £277m. To make the medicines cost effective on their own a price reduction of 8.6% to 9.7% is required. The central estimate of the net benefit with price reductions is £4,453m.

Scenario 3 shows the potential scale of loss if the selection is only high risk medicines with an immature evidences base. Speeding up access results in higher effective prices than exist by waiting for more evidence on the true value of the health gain. The net loss over the 20 year modelling period for the 5 cohorts of technologies is £4,266m.

These scenarios have been selected to illustrate the effects of selecting technologies with different degrees of certainty about the benefits and other scenarios exist. In general, as the uncertainty surrounding a technology increases its value for money is likely to fall.

The actual technologies chosen may not precisely match the characteristics assumed here or the scenarios as set out above. The scenarios of course also assume that there are enough technologies forthcoming for the AAC to be able to select them.

## Further detail of analysis

### *Direct effects*

Selection for the AAC entails changes in the NHS's use of products, compared to the counterfactual in which they are not selected for the AAC. Specifically:

- They may be used by patients in an EAMS scheme before marketing authorisation, if appropriate
- Their appraisal and launch will be brought forward
- Their uptake may be more rapid
- Their ultimate peak use may be greater
- Their probability of approval by NICE may increase
- There may be an impact on price

The following sections evaluate these direct effects in respect of pharmaceuticals and medical technologies. Not all technologies will require all aspects of the pathway. The modelling for this impact assessment assumes that i) achieving commercial agreements is not always straightforward, and ii) ex ante knowledge of the products is not available. Therefore AAC will have to manage the portfolio carefully.

### *Ultimate impacts*

Changes in use of the product may lead ultimately to changes in the following outcomes, whose magnitudes are estimated in this Impact Assessment:

- Health gained by patients receiving the product (and consequent Wider Societal Impacts)
- Costs to the NHS of purchasing the product, and associated NHS cost impacts, including savings. (NHS cost impacts ultimately correspond to health impacts for patients elsewhere, and the consequent Wider Societal Impacts)
- Revenues and profits to companies supplying the products
- R&D investment, of which a portion will be in the UK, creating "spill-over" benefits for the UK economy

The magnitudes of these outcomes are estimated separately in respect of pharmaceuticals and medical technologies in the following sections.

## Number and characteristics of products affected

The actual products that will be selected for the AAC are unknown. This analysis therefore considers a plausible representative scenario as follows:

- There are 5 transformative technologies per annum selected for the AAC – one each from the range of technology types as defined on page 9
- Products are assumed to have an average annual peak sales (that is, the level of sales after full uptake is reached) of **£20m pa** if used in the NHS under the counterfactual scenario**.** Clearly, some products will have a greater value of sales than others, but this figure is consistent with analysis of the future pipeline of products considered likely to qualify for the AAC. This gives an annual peak sales for each new cohort of **£100m**. Therefore, in steady state, once the programme has been running for 5 years (i.e. the fifth cohort has commenced) the annual value of technologies managed by AAC is **£500m**.
- Products generate savings to the NHS – by substituting for other interventions, or by obviating some other costs. Looking at health technology appraisals used for NICE guideline from 2011-2015 suggests medicines can deliver savings which are equivalent to **50%** of their purchase cost (including the saving that results from no longer using the alternative treatment – usually the main source of savings). This figure is broadly consistent with historical data for new drug approvals. Medical technology products and devices are currently subject to assessment appraisals from NICE. Some products can be cost effective (delivering more QALY gains for same price) or cost saving. The lack of an appraisal system can lead to cost effective devices have zero or low take up across the NHS. Note that, while many technologies generate savings by replacing existing ones, it may be expected that "transformative" products selected for the AAC are more likely to provide novel, additional benefits, rather than substitute for existing treatments – such that their proportionate savings would be lower than other products.
- Products are assumed to have an effective patent life (the interval between launch and patent expiry) of **12 years** in the counterfactual scenario**.**

## Option 0: Do nothing. Definition of counterfactual scenario

The following assumptions are made about the products selected for AAC under the counterfactual scenario – that is, if the AAR proposals were not implemented.

- The products have an **80% probability of approval** by NICE in the counterfactual scenario
- The product set, as a whole, would have an ICER of **£32,000 / QALY** on average if used in the NHS. In reality the actual cost effectiveness will vary from medicine to medicine. This assumption is above the upper limit of the normal NICE cost/QALY range, to reflect that:

    - some products may be approved at the higher £50,000 / QALY ICER applied for products at the End of Life
    - some products may be Highly Specialised Technologies with a substantially higher cost / QALY ICER
- in accordance with the assumption above, 20% of products are expected not to be approved under the counterfactual scenario, implying that their cost per QALY is in excess of the upper range for which NICE grant approval.
- Products follow a linear trajectory of uptake following launch, reaching peak use after **4** years.

## Scenario 1: Accelerated Access Collaborative selects medical technologies with mature evidence base (lowest risk)

Scenario 1 represents a selection of technologies by the AAC which can be regarded as low risk. This is because the information (particularly relating to health gain) about them has a high level of certainty from a mature evidence base. The following modelling assumptions apply:

- The AAC selects 5 products, of which
    - 2 are cost effective medical technologies
    - 3 are cost saving medical technologies
- all 5 products selected for AAC have a probability of approval of 100% in the accelerated scenario
- The effective launch of the product (following marketing authorisation) will be brought forward by 1 **year**, compared to the counterfactual scenario
- Uptake of the product will follow the same rapid trajectory as the counterfactual scenario, reaching peak use after **3 years**
- The peak level of use for products selected for the AAC will be the same as in the counterfactual.
- No price negotiation takes place - under this option prices paid for the products are the same as in the counterfactual scenario

## Effects of the Accelerated Access under option 1

Under this scenario, the only real effect is that products are available sooner to patients on the NHS. Selection by the collaborative means use of the product is promoted by the members of the collaborative.

- The effective launch of the product will be brought forward by **1 year**, compared to the counterfactual scenario
- Uptake of the product will follow a more rapid trajectory than in the counterfactual scenario, reaching peak use after **3 years** instead of 4
- The peak level of use for products selected for the AAC will be the same compared to the counterfactual.

## Results

Details about cost effective and cost saving medical technologies can be found in Annex A. In particular, the annex shows the uptake rates and peak sales profile for each product.

The table below shows the details for the change in NHS expenditure, impacts on patients and industry profits for each cohort of medical technology products over their life cycle.

Figure 1: Impacts of each product in a single cohort

| **IMPACTS (Lifetime per cohort)** | | **Medtech** | | |
|---|---|---|---|---|
| | ***Scenarios*** | *MT CE* | *MT CS* | ***MT agg*** |
| | *Product numbers affected pa* | 2 | 3 | **5** |
| | *Price effect (vs counterfactual)* | 0% | 0% | |
| ***Impacts*** | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 380 | -570 | **-190** |
| | Accelerated Access spend on products, net of savings, £m | 550 | -825 | **-275** |
| | **Net change in spend due to AA, £m** | 170 | -255 | **-85** |
| *Patients* | QALY gains (from net change in spend) | 17,000 | 17,000 | **34,000** |

| | | | | |
|---|---|---|---|---|
| | WSI gains (from QALY gains), £m | 192 | 237 | **429** |
| | **Value of QALYs and WSIs gained, £m** | 1,212 | 1,257 | **2,469** |
| | QALYs displaced (from net change in spend) | 11,333 | 0 | **11,333** |
| | WSIs displaced (from QALYs displaced), £m | 158 | 0 | **158** |
| | **Value of QALYs and WSIs displaced, £m** | 838 | 0 | **838** |
| *Industry* | **UK profits, £m** | 8.9 | 13.4 | **22** |
| | **UK R&D spillovers, £m** | 4.6 | 6.9 | **11** |
| *Admin* | Accelerated Access Collaborative | - | - | **0.22** |
| | Innovation Support Schemes | - | - | **17** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 1,217 | 1,264 | **2,480** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 838 | 0 | **855** |
| *Net benefit* | *Benefits minus costs, £m* | 379 | 1,264 | **1,625** |

Figure 1 shows the outcome for a basket of selected technologies that contains 2 cost effective medical technology (MT CE) and 3 cost saving medical technology (MT CS) products. For MT CE, there is an increase in net expenditure of £170m across the 2 products. This delivers an additional health gain to paitents of 17,000 QALYs[9] who receive the intervention, which has a total value of £1,212 (including wider societal benefits). As the money to pay for it is found from elsewhere 11,333 QALYs are displaced, which has a value of £838m. Net profits to UK shareholder of life sciences companies increase by £8.9m over the period. This generates an economic benefit of £4.6m from R&D spillover effects. The net benefit is £379m.

For MT CS products, there is an overall fall on the NHS budget of £255m as expenditure switches to these products. Typically, the savings come from efficiencies within the NHS care pathway. The freed up resoure can be spent elsewhere by the NHS and generates 17,000 additional QALYs[10]. The value of this is £1,257m which is slightly higher than the MT CE product as the wider societal impacts are slightly greater. As the introduction of these technologies are cash releasing, additional resources do not need to be found to pay for them, so there are no displaced QALYs. For the 3 technologies selected in this category, the net benefit is £1,264m.

The final column shows the aggregate affect of all 5 technologies selected. It also includes the cost of £17.2m which is used to provide support (as described on page 7) to industry so that innovative products are developed to meet the NHS needs and to support adoption across the NHS: £15m of which is used to develop capacity across the Academic Health Science Network (AHSNs); and £2m through a Small- and Medium- sized Enterprise (SME) grant scheme designed to fund R&D. This is the same for all options. Overall, the net benefit is £1,625m.

## Running the AAC for 5 years

If we extrapolate the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 (10 MT CE and 15 MT CS). The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 2: Impacts of AAC operating over 5 years

| **PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation)** | **Medtech** | | |
|---|---|---|---|
| ***Scenarios*** | *MT CE* | *MT CS* | ***MT agg*** |
| *Product numbers affected pa* | 2 | 3 | **5** |
| *Total products* | 10 | 15 | **25** |
| ***Impacts*** | | | |

[9] Modelling assumes selected product has an incremental cost effectiveness ratio of £10,000 per QALY

[10] Modelling assumes generates QALYs at the typical NHS marginal rate of £15,000 per QALY

| | | | | |
|---|---|---|---|---|
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 1,647 | -2,470 | **-823** |
| | Accelerated Access spend on products, net of savings, £m | 2,410 | -3,614 | **-1,205** |
| | **Net change in spend due to AA, £m** | 763 | -1,144 | **-381** |
| *Patients* | QALY gains (from net change in spend) | 76,279 | 76,279 | **152,557** |
| | WSI gains (from QALY gains), £m | 862 | 1,062 | **1,925** |
| | **Value of QALYs and WSIs gained, £m** | 5,439 | 5,639 | **11,078** |
| | QALYs displaced (from net change in spend) | 50,852 | 0 | **50,852** |
| | WSIs displaced (from QALYs displaced), £m | 708 | 0 | **708** |
| | **Value of QALYs and WSIs displaced, £m** | 3,759 | 0 | **3,759** |
| *Industry* | **UK profits, £m** | 35 | 53 | **88** |
| | **UK R&D spillovers, £m** | 18 | 27 | **45** |
| *Admin* | Accelerated Access Collaborative | - | - | **1.1** |
| | Early Access to Medicines Scheme | - | - | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 5,457 | 5,666 | **11,123** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 3,759 | 0 | **3,845** |
| *Net benefit* | *Benefits minus costs, £m* | 1,698 | 5,666 | **7,278** |

The discounted net increase in expenditure over the lifetime of both product types is shown above if the AAC is run for 5 years. In aggregate the total benefit is £11,123m from the net gain in health and wider societal impacts. The total cost is £3,845m resulting in a net benefit £7,278m.

## Summary of scenario 1

The table below shows the cost benefit and net present value for the scenario of option 1

| | Cost | Benefit | Net present Value |
|---|---|---|---|
| Option 1 | £3,845m | £11,123m | £7,278m |

## Scenario 2: Accelerated Access Collaborative selects medical technologies and medicines with mature evidence base (medium risk)

Scenario 2 represents a selection of technologies by the AAC that has a higher degree of risk than option 1 and is the scenario where the portfolio most closely follows the policy intention. The information (particularly relating to health gain) about them still has a high level of certainty from a mature evidence base. However, the portfolio now includes 2 medicine at or near the upper end of the NICE approval range[11]; of which 1 medicine is accelerated by 2 year and the other is accelerated by 2 year and is made available to patients through EAMS.

The following modelling assumptions apply:

- The AAC selects 5 products, of which
    - 1 is a medicine (accelerated access)
    - 1 is a medicine (EAMS)
    - 1 is cost effective medical technologies
    - 2 are cost saving medical technologies
- all 5 products selected for AAC have a probability of approval of 100% in the accelerated scenario
- The effective launch of medical technology products will be brought forward by **1 year**, compared to the counterfactual scenario
- The effective launch of medicines will be brought forward by **2 year**, compared to the counterfactual scenario
- Uptake of the product will follow the same rapid trajectory as the counterfactual scenario, reaching peak use after **3 years**
- The peak level of use for products selected for the AAC will be the same as in the counterfactual.

In this scenario, price reductions are required for medicines in order for the policy of accelerating their access to be a value-generating proposition. Different price (cost-effectiveness) assumptions are reflected in the low and medium outcome estimate for this portfolio. In the high outcome estimate, which incorporates the price reduction in the medium outcome, the counterfactual cost effectiveness is relaxed to £30,000 per QALY for medicines. This sets out the impact relative to NICE's cost-effectiveness threshold (effectively assuming that new medicines displace NHS care of a similar level of cost effectiveness.

| Outcome estimate | Price level | Counterfactual cost effectiveness |
|---|---|---|
| Low | No price reductions for any of the 5 technologies | £15,000 per QALY for all technologies |
| Mid | Price reduction for medicines but not for medical technologies | £15,000 per QALY for all technologies |
| High | Price reduction for medicines but not medical technologies | £15,000 per QALY for medical technologies<br>£30,000 per QALY for medicines |

[11] For modelling purposes, we have used an effective cost effectiveness of £32,000 per QALY as explained on page 16

## Effects of the Accelerated Access under scenario 2

Under this scenario, the only real effect is that products are available sooner to patients on the NHS. Compliance with the collaborative criteria means that NICE approval is completed as part of the accelerated access pathway.

- The effective launch of the medical technology product is brought forward by **1 year**, compared to the counterfactual scenario
- The effective launch of the medical technology product is brought forward by **2 year**, compared to the counterfactual scenario
- Uptake of the product follows a more rapid trajectory than in the counterfactual scenario, reaching peak use after **3 years** instead of 4
- The peak level of use for products selected for the AAC is the same as in the counterfactual.

## Low value estimate results

The results for the low value outcome is shown in figure 3

Figure 3: Impacts of each product in a single cohort

| IMPACTS (Lifetime per cohort) | | Pharma | | | Medtech | | | Aggregate |
|---|---|---|---|---|---|---|---|---|
| | ***Scenarios*** | *Accel'd* | *EAMS* | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| | *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | **5** |
| | *Price effect (vs counterfactual)* | 0.0% | 0.0% | | 0% | 0% | | |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 95 | 95 | **190** | 190 | -380 | **-190** | **0** |
| | Accelerated Access spend on products, net of savings, £m | 150 | 148 | **298** | 275 | -550 | **-275** | **23** |
| | **Net change in spend due to AA, £m** | 55 | 53 | **108** | 85 | -170 | **-85** | **23** |
| *Patients* | QALY gains (from net change in spend) | 1,719 | 1,792 | **3,511** | 8,500 | 11,333 | **19,833** | **23,344** |
| | WSI gains (from QALY gains), £m | 19 | 20 | **40** | 96 | 158 | **254** | **294** |
| | **Value of QALYs and WSIs gained, £m** | 123 | 128 | **250** | 606 | 838 | **1,444** | **1,694** |
| | QALYs displaced (from net change in spend) | 3,667 | 3,510 | **7,177** | 5,667 | 0 | **5,667** | **12,844** |
| | WSIs displaced (from QALYs displaced), £m | 51 | 49 | **100** | 79 | 0 | **79** | **179** |
| | **Value of QALYs and WSIs displaced, £m** | 271 | 260 | **531** | 419 | 0 | **419** | **949** |
| *Industry* | **UK profits, £m** | 1.2 | 1.1 | **2.3** | 4.5 | 8.9 | **13.4** | **16** |
| | **UK R&D spillovers, £m** | 0.6 | 0.6 | **1.2** | 2.3 | 4.6 | **6.9** | **8** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **0.22** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **17** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 124 | 129 | **254** | 608 | 842 | **1,451** | **1,702** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 271 | 260 | **531** | 419 | 0 | **419** | **966** |
| *Net benefit* | *Benefits minus costs, £m* | -147 | -130 | **-277** | 189 | 842 | **1,032** | **736** |

For the two medicines, their accelerated use means that amount spent on them increases over their patent life by £55m for the accelerated only medicine and by £53m for the accelerated medicine also available through the early access scheme (EAMS). The increased expenditure is slightly lower because the manufacturer makes it available to patients without charge while participating in EAMS. Owing to the assumption that the new medicines' effective ICER is £32,000 per QALY, and the displaced NHS spends' is £15,000 per QALY, more health gain is displaced than is delivered by the new medicines. The net loss for the accelerated medicine is £147m and for the EAMS medicine is £130m, making the combined loss £277m. The outcomes for each individual medical technology product is the same as for

option 1, but the aggregate effect is a lower net benefit as fewer of them have been selected. The net benefit for the 3 medical technology products is £1,032m. The overall net benefit for the portfolio of 5 technologies is £736m. The cost of operating the schemes and providing support to SMEs is the same as for option 1 at £17.2m.

## Running the AAC for 5 years

In a similar fashion to scenario 1, if we extrapolate the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 (10 medicines and 15 medical technology products). The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 4: Impacts of AAC operating over 5 years

| PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation) | | Pharma | | | Medtech | | | Aggregate |
|---|---|---|---|---|---|---|---|---|
| | ***Scenarios*** | *Accel'd* | EAMS | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| | *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | |
| | *Total products* | 5 | 5 | **10** | 5 | 10 | **15** | **25** |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 409 | 404 | **813** | 823 | -1,647 | **-823** | **-11** |
| | Accelerated Access spend on products, net of savings, £m | 657 | 639 | **1,296** | 1,205 | -2,410 | **-1,205** | **91** |
| | **Net change in spend due to AA, £m** | 249 | 235 | **483** | 381 | -763 | **-381** | **102** |
| *Patients* | QALY gains (from net change in spend) | 7,712 | 7,977 | **15,689** | 38,139 | 50,852 | **88,992** | **104,680** |
| | WSI gains (from QALY gains), £m | 87 | 90 | **177** | 431 | 708 | **1,139** | **1,317** |
| | **Value of QALYs and WSIs gained, £m** | 550 | 569 | **1,119** | 2,720 | 3,759 | **6,479** | **7,598** |
| | QALYs displaced (from net change in spend) | 16,574 | 15,648 | **32,222** | 25,426 | 0 | **25,426** | **57,648** |
| | WSIs displaced (from QALYs displaced), £m | 231 | 218 | **449** | 354 | 0 | **354** | **803** |
| | **Value of QALYs and WSIs displaced, £m** | 1,225 | 1,157 | **2,382** | 1,880 | 0 | **1,880** | **4,262** |
| *Industry* | **UK profits, £m** | 5 | 4 | **9** | 18 | 35 | **53** | **62** |
| | **UK R&D spillovers, £m** | 2 | 2 | **5** | 9 | 18 | **27** | **32** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **1.1** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 557 | 575 | **1,123** | 2,729 | 3,777 | **6,506** | **7,629** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 1,225 | 1,157 | **2,382** | 1,880 | 0 | **1,880** | **4,347** |
| *Net benefit* | *Benefits minus costs, £m* | -668 | -581 | **-1,259** | 849 | 3,777 | **4,626** | **3,283** |

Running the programme for 5 years means that the combined net loss from the 2 medicines is £1,259m. The net gain from the medical technology devices is £4,626m, meaning that the overall net gain is £3,283m. There is an overall net cost to the NHS of £102m over 15 years as the savings from the medical technology products (£381m) partially offsets the extra cost of the medicines. Although this has a positive net benefit, scenario 1 offers better value for money.

## Mid value estimate results

The results for the low value outcome is shown in figure 5

Figure 5: Impacts of each product in a single cohort

| IMPACTS (Lifetime per cohort) | Pharma | | | Medtech | | | Aggregate |
|---|---|---|---|---|---|---|---|
| ***Scenarios*** | *Accel'd* | *EAMS* | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | **5** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | *Price effect (vs counterfactual)* | 9.7% | 8.6% | | 0% | 0% | | |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 95 | 95 | **190** | 190 | -380 | **-190** | **0** |
| | Accelerated Access spend on products, net of savings, £m | 121 | 122 | **243** | 275 | -550 | **-275** | **-32** |
| | **Net change in spend due to AA, £m** | 26 | 27 | **53** | 85 | -170 | **-85** | **-32** |
| *Patients* | QALY gains (from net change in spend) | 1,719 | 1,792 | **3,511** | 8,500 | 11,333 | **19,833** | **23,344** |
| | WSI gains (from QALY gains), £m | 19 | 20 | **40** | 96 | 158 | **254** | **294** |
| | **Value of QALYs and WSIs gained, £m** | 123 | 128 | **250** | 606 | 838 | **1,444** | **1,694** |
| | QALYs displaced (from net change in spend) | 1,719 | 1,792 | **3,511** | 5,667 | 0 | **5,667** | **9,178** |
| | WSIs displaced (from QALYs displaced), £m | 24 | 25 | **49** | 79 | 0 | **79** | **128** |
| | **Value of QALYs and WSIs displaced, £m** | 127 | 133 | **260** | 419 | 0 | **419** | **678** |
| *Industry* | **UK profits, £m** | 0.5 | 0.6 | **1.1** | 4.5 | 8.9 | **13.4** | **14** |
| | **UK R&D spillovers, £m** | 0.3 | 0.3 | **0.6** | 2.3 | 4.6 | **6.9** | **7** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **0.22** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **17** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 123 | 129 | **252** | 608 | 842 | **1,451** | **1,702** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 127 | 133 | **260** | 419 | 0 | **419** | **695** |
| *Net benefit* | *Benefits minus costs, £m* | -4 | -4 | **-8** | 189 | 842 | **1,032** | **1,006** |

For the mid value estimate, the model assumes that genuine price reductions can be achieved for the accelerated medicine and the EAMS medicine of 9.7% and 8.6% respectively. This is the level of reduction required so that health gain from the selected medicines is the same as the health gain displaced by care foregone elsewhere. There is still a small net loss for each medicine as the wider societal impacts from the medicines is not as great as that for the displaced care[12]. The increase in expenditure is up to £27m per medicine.

The expenditure and net benefit for the medical technology products remains the same as for scenario 1 and the low value estimate for scenario 2. Therefore, the net benefit is now £1,006m for each cohort.

## Running the AAC for 5 years

As with previous estimates, if we extrapolate the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 (10 medicines and 15 medical technology products). The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 6: Impacts of AAC operating over 5 years

| **PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation)** | | **Pharma** | | | **Medtech** | | | **Aggregate** |
|---|---|---|---|---|---|---|---|---|
| | ***Scenarios*** | *Accel'd* | *EAMS* | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| | *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | |
| | *Total products* | 5 | 5 | **10** | 5 | 10 | **15** | **25** |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 409 | 404 | **813** | 823 | -1,647 | **-823** | **-11** |
| | Accelerated Access spend on products, net of savings, £m | 530 | 528 | **1,058** | 1,205 | -2,410 | **-1,205** | **-147** |
| | **Net change in spend due to AA, £m** | 122 | 124 | **245** | 381 | -763 | **-381** | **-136** |
| *Patients* | QALY gains (from net change in spend) | 7,712 | 7,977 | **15,689** | 38,139 | 50,852 | **88,992** | **104,680** |
| | WSI gains (from QALY gains), £m | 87 | 90 | **177** | 431 | 708 | **1,139** | **1,317** |

[12] This is because WSI across all ICD codes is estimated to be £13,950 per QALY compared to £11,600 for a narrow group of ICD codes (cancer, cardiovascular, respiratory) likely to disease areas of new medicines

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Value of QALYs and WSIs gained, £m** | 550 | 569 | **1,119** | 2,720 | 3,759 | **6,479** | **7,598** |
| | QALYs displaced (from net change in spend) | 8,102 | 8,259 | **16,361** | 25,426 | 0 | **25,426** | **41,787** |
| | WSIs displaced (from QALYs displaced), £m | 113 | 115 | **228** | 354 | 0 | **354** | **582** |
| | **Value of QALYs and WSIs displaced, £m** | 599 | 611 | **1,209** | 1,880 | 0 | **1,880** | **3,089** |
| *Industry* | **UK profits, £m** | 2 | 2 | **5** | 18 | 35 | **53** | **58** |
| | **UK R&D spillovers, £m** | 1 | 1 | **2** | 9 | 18 | **27** | **30** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **1.1** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 553 | 572 | **1,121** | 2,729 | 3,777 | **6,506** | **7,627** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 599 | 611 | **1,209** | 1,880 | 0 | **1,880** | **3,174** |
| *Net benefit* | *Benefits minus costs, £m* | -45 | -38 | **-88** | 849 | 3,777 | **4,626** | **4,453** |

The price reductions for the two medicines mean that the combined net loss over the 20 year period has been reduced from £1,259m to £88m. The net gain from the medical technology devices remains at £4,626m meaning that the overall net gain is £4,453m up from £3,283m. There is a net saving to the NHS of £136m as the savings from the medical technology products is greater than the extra cost of the medicines. This suggests the programme can take some risks and be cost neutral overall. However, this does depend on the NHS England Commercial Unit being able to achieve true price reductions of between 8.6% and 9.7%. This unit is new and the likelihood of it being able to deliver this level of reduction is unknown. One should note that even with these price reductions for the medicines, scenario 1, which focuses just on medical technology, still offers better value for money albeit from a less comprehensive range of technologies.

## High value estimate

The results for the high value estimate are shown in figure 7. This estimate assumes that the same price reductions are achieved as for the mid value estimate of this scenario. In addition, it adopts an incremental cost effectiveness ratio of the care displaced is £30,000 per QALY rather than £15,000. This has the effect of halving the amount of health loss from the displaced NHS activity.

Figure 7: Impacts of each product in a single cohort

| **IMPACTS (Lifetime per cohort)** | | **Pharma** | | | **Medtech** | | | **Aggregate** |
|---|---|---|---|---|---|---|---|---|
| | ***Scenarios*** | *Accel'd* | *EAMS* | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| | *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | **5** |
| | *Price effect (vs counterfactual)* | 9.7% | 8.6% | | 0% | 0% | | |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 95 | 95 | **190** | 190 | -380 | **-190** | **0** |
| | Accelerated Access spend on products, net of savings, £m | 121 | 122 | **243** | 275 | -550 | **-275** | **-32** |
| | **Net change in spend due to AA, £m** | 26 | 27 | **53** | 85 | -170 | **-85** | **-32** |
| *Patients* | QALY gains (from net change in spend) | 1,719 | 1,792 | **3,511** | 8,500 | 11,333 | **19,833** | **23,344** |
| | WSI gains (from QALY gains), £m | 19 | 20 | **40** | 96 | 158 | **254** | **294** |
| | **Value of QALYs and WSIs gained, £m** | 123 | 128 | **250** | 606 | 838 | **1,444** | **1,694** |
| | QALYs displaced (from net change in spend) | 863 | 895 | **1,759** | 5,667 | 0 | **5,667** | **7,425** |
| | WSIs displaced (from QALYs displaced), £m | 12 | 12 | **24** | 79 | 0 | **79** | **103** |
| | **Value of QALYs and WSIs displaced, £m** | 64 | 66 | **130** | 419 | 0 | **419** | **549** |
| *Industry* | **UK profits, £m** | 0.5 | 0.6 | **1.1** | 4.5 | 8.9 | **13.4** | **14** |
| | **UK R&D spillovers, £m** | 0.3 | 0.3 | **0.6** | 2.3 | 4.6 | **6.9** | **7** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **0.22** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **17** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 123 | 129 | **252** | 608 | 842 | **1,451** | **1,702** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 64 | 66 | **130** | 419 | 0 | **419** | **566** |
| *Net benefit* | *Benefits minus costs, £m* | 60 | 62 | **122** | 189 | 842 | **1,032** | **1,136** |

In this estimate, the number of displaced QALYs falls to 863 and 895 for the accelerated medicine and the EAMS medicine respectively. This means they deliver net benefits to patients worth £122m over their lifetime in aggregate. The results for the medical technologies are unchanged.

## Running the AAC for 5 years

As with previous estimates, if we extrapolate the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 (10 medicines and 15 medical technology products). The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 8: Impacts of AAC operating over 5 years

| **PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation)** | | **Pharma** | | | **Medtech** | | | **Aggregate** |
|---|---|---|---|---|---|---|---|---|
| | ***Scenarios*** | | | ***agg*** | *MT CE* | *MT CS* | ***MT agg*** | |
| | *Product numbers affected pa* | 1 | 1 | **2** | 1 | 2 | **3** | |
| | *Total products* | 5 | 5 | **10** | 5 | 10 | **15** | **25** |
| ***Impacts*** | | | | | | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 409 | 404 | **813** | 823 | -1,647 | **-823** | **-11** |
| | Accelerated Access spend on products, net of savings, £m | 531 | 528 | **1,058** | 1,205 | -2,410 | **-1,205** | **-146** |
| | **Net change in spend due to AA, £m** | 122 | 124 | **246** | 381 | -763 | **-381** | **-136** |
| *Patients* | QALY gains (from net change in spend) | 7,712 | 7,977 | **15,689** | 38,139 | 50,852 | **88,992** | **104,680** |
| | WSI gains (from QALY gains), £m | 87 | 90 | **177** | 431 | 708 | **1,139** | **1,317** |
| | **Value of QALYs and WSIs gained, £m** | 550 | 569 | **1,119** | 2,720 | 3,759 | **6,479** | **7,598** |
| | QALYs displaced (from net change in spend) | 4,068 | 4,125 | **8,193** | 25,426 | 0 | **25,426** | **33,620** |
| | WSIs displaced (from QALYs displaced), £m | 57 | 57 | **114** | 354 | 0 | **354** | **468** |
| | **Value of QALYs and WSIs displaced, £m** | 301 | 305 | **606** | 1,880 | 0 | **1,880** | **2,485** |
| *Industry* | **UK profits, £m** | 2 | 2 | **5** | 18 | 35 | **53** | **58** |
| | **UK R&D spillovers, £m** | 1 | 1 | **2** | 9 | 18 | **27** | **30** |
| *Admin* | Accelerated Access Partnership | - | - | **-** | - | - | **-** | **1.1** |
| | Early Access to Medicines Scheme | - | - | **-** | - | - | **-** | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 553 | 572 | **1,121** | 2,729 | 3,777 | **6,506** | **7,627** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 301 | 305 | **606** | 1,880 | 0 | **1,880** | **2,570** |
| *Net benefit* | *Benefits minus costs, £m* | 253 | 267 | **515** | 849 | 3,777 | **4,626** | **5,057** |

If the AAC is operated for 5 years, the net benefit from the 2 selected medicines is £515m. They will require additional expenditure of £246m over 20 years. The 3 medical technology products release £381m giving an overall net budgetary saving for the portfolio of £136m. The 5 technologies deliver 104,680 additional QALYs but displace 33,360 QALYs from elsewhere. The overall net benefit is £5,057m.

## Summary of Scenario 2

The table below shows the cost, benefit and net present value for Scenario 2 where the assumptions have been varied to create low, mid and high value estimates.

| Option 2 | Cost | Benefit | Net present Value |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Low value estimate | £4,347m | £7,629m | £3,283m |
| Mid value estimate | £3,174m | £7,627m | £4,453m |
| High value estimate | £2,570m | £7,627m | £5,057m |

The low value estimate has the lowest NPV because no price reductions of the medicines are achieved and those medicines have a net loss of £1,259m owing to the displaced care. Price reductions of between 8.6% and 9.7% means they are cost neutral and the NPV increases to £515m for the medicines. Success depends on the ability of NHS England Commercial Unit to deliver price reduction, which is unknown at this stage. If the medicines are assumed to displace NHS care that had an ICER of £30,000 per QALY rather than £15,000 per QALY then the NPV rises to £4,453m as value of the opportunity cost of the care displaced is lower. All estimates of scenario 2 have a lower NPV than option 1.

### Pressure on NHS medicines spend

The above information sets out the cost and benefits in line with the Green Book. As each cohort of technologies are selected, the 2 medicines put pressure on NHS medicines spending as a result of bringing forward the point from which they are available to patients (without bringing forward the time when patent expires). This has a significant and enduring cost impact as successive cohorts of earlier adopted products come through – i.e. it is not a first year one-off impact. Where no price reductions are achieved, this cost pressure is £50m per year for the 2 medicines in steady state which is reached 5 years after AAC is launched. If a price reduction of 8.6% - 9.7% is achieved, then the annual cost pressure reaches to £38m at its peak (after four years) and then falls to £6m per year in steady state. Steady state is not reached until 13 years after launch. Both scenarios assume that the AAC is permanent.

## Scenario 3: Accelerated Access Collaborative selects 5 medicines with immature evidence base (highest risk)

Scenario 3 is not the intended policy but shows an outcome that might occur if the AAC did not mitigate risks and instead selected a portfolio of only high risk technologies. The illustrative technologies in this scenario are the medicines (managed access),that have an immature evidence base about their effectiveness[13]. The model assumes the AAC selects all 5 technologies in the portfolio to be of this type.

The following modelling assumptions apply:

- The AAC selects 5 medicine managed access technologies
- all 5 products selected for AAC have a probability of approval of 100% in the accelerated scenario
- The effective launch of medical technology products is brought forward by **1 year**, compared to the counterfactual scenario
- The effective launch of medicines is brought forward by **2 year**, compared to the counterfactual scenario
- Uptake of the product will follow the same rapid trajectory as the counterfactual scenario, reaching peak use after **3 years**
- The peak level of use for products selected for the AAC is the same as in the counterfactual.
- The uncertainty of the evidence base increases the ICER to **£45,000 per QALY**. As the value of the corresponding marginal increase in health is half the gross value, this equates to a 25% increase in the price of a medicines.
- A price is agreed at the point of conditional approval. The manufacturer agrees a 10% reduction from the agreed price during the managed access period of 2 years

In this scenario, uncertainty on the health gain from an immature evidence base leads to poor value for money. Two outcomes are estimated. A mid value outcome has the biggest loss while a higher value outcome has some of the losses mitigated by calculation with reference to a displaced ICER of £30,000 per QALY. More details are shown in the table below.

| Outcome estimate | Price level | Counterfactual cost effectiveness |
|---|---|---|
| Mid | Effective price increase of 50% resulting in ICER of £45,000 per QALY | £15,000 per QALY for all 5 medicines |
| High | Effective price increase of 50% resulting in ICER of £45,000 per QALY | £30,000 per QALY for 5 medicines |

## Effects of the Accelerated Access under scenario 3

Under this option, the real effect is that 5 medicines are available sooner to patients on the NHS. In particular, as the evidence base is immature, under the counterfactual the medicines would not have been approved by NICE. Compliance with the collaborative criteria means that NICE approval is completed as part of the accelerated access pathway .

- The effective launch of the medical technology product is brought forward by **1 year**, compared to the counterfactual scenario

[13] Allowing consideration of medicines with an immature evidence base runs the risk of creating an incentive for firms to be selective (or withhold) about the data they submit.

- The effective launch of the medical technology product is brought forward by **2 year**, compared to the counterfactual scenario
- Uptake of the product follows a more rapid trajectory than in the counterfactual scenario, reaching peak use after **3 years** instead of 4
- The peak level of use for products selected for the AAC is the same as in the counterfactual.

## Mid value estimate results

The results for the low value outcome is shown in figure 9.

Figure 9: Impacts of each product in a single cohort

| IMPACTS (Lifetime per cohort) | | Pharma | Aggregate |
|---|---|---|---|
| | ***Scenarios*** | *Managed Access* | |
| | *Product numbers affected pa* | 1 | **5** |
| | *Price effect (vs counterfactual)* | 0.0 | |
| ***Impacts*** | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 100 | **500** |
| | Accelerated Access spend on products, net of savings, £m | 152 | **744** |
| | **Net change in spend due to AA, £m** | 52 | **244** |
| *Patients* | QALY gains (from net change in spend) | 1,049 | **5,243** |
| | WSI gains (from QALY gains), £m | 15 | **73** |
| | **Value of QALYs and WSIs gained, £m** | 78 | **388** |
| | QALYs displaced (from net change in spend) | 3,465 | **16,256** |
| | WSIs displaced (from QALYs displaced), £m | 48 | **226** |
| | **Value of QALYs and WSIs displaced, £m** | 256 | **1,202** |
| *Industry* | **UK profits, £m** | 1.1 | **5** |
| | **UK R&D spillovers, £m** | 0.6 | **3** |
| *Admin* | Accelerated Access Partnership | - | **0.22** |
| | Early Access to Medicines Scheme | - | **17** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 79 | **398** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 256 | **1,219** |
| *Net benefit* | *Benefits minus costs, £m* | -177 | **-821** |

For each medicine (managed access) the net increase in expenditure is £52m over the lifetime of its use. As the effective ICER has increased to £45,000 per QALY the extra £52m delivers only 1,049 QALYs to patients (compared to 1,719m QALYs from £55m in figure 3). The net loss is £177m. For all 5 managed access medicines the increase in expenditure is £244m over the 15 year modelling period and the net loss is £821m.

## Running the AAC for 5 years

Extrapolating the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 all of which are medicines with managed access. The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 12: Impacts of AAC operating over 5 years

| PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation) | Pharma | Aggregate |
|---|---|---|
| ***Scenarios*** | *Managed Access* | |

| | | | |
|---|---|---|---|
| | *Product numbers affected pa* | 5 | **5** |
| | *Total products* | 25 | **25** |
| ***Impacts*** | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 2,043 | **2,043** |
| | Accelerated Access spend on products, net of savings, £m | 3,332 | **3,332** |
| | **Net change in spend due to AA, £m** | 1,289 | **1,289** |
| *Patients* | QALY gains (from net change in spend) | 29,206 | **29,206** |
| | WSI gains (from QALY gains), £m | 407 | **407** |
| | **Value of QALYs and WSIs gained, £m** | 2,159 | **2,159** |
| | QALYs displaced (from net change in spend) | 85,918 | **85,918** |
| | WSIs displaced (from QALYs displaced), £m | 1,196 | **1,196** |
| | **Value of QALYs and WSIs displaced, £m** | 6,351 | **6,351** |
| *Industry* | **UK profits, £m** | 23 | **23** |
| | **UK R&D spillovers, £m** | 12 | **12** |
| *Admin* | Accelerated Access Partnership | - | **1.1** |
| | Early Access to Medicines Scheme | - | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 2,193 | **2,171** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 6,351 | **6,436** |
| *Net benefit* | *Benefits minus costs, £m* | -4,158 | **-4,266** |

Running the programme for 5 years the increase in expenditure is £1,289m. The net loss is £4,266m.

## High value estimate results

As with scenario 2, this "high" value estimate for scenario 3 flexes the ICER assumption for the displaced NHS care from £15,000 per QALY to £30,000 per QALY. The results for the low value outcome is shown in figure 13

Figure 13: Impacts of each product in a single cohort

| **IMPACTS (Lifetime per cohort)** | | **Pharma** | **Aggregate** |
|---|---|---|---|
| | ***Scenarios*** | *Managed Access* | |
| | *Product numbers affected pa* | 1 | **5** |
| | *Price effect (vs counterfactual)* | 0.0 | |
| ***Impacts*** | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 100 | **500** |
| | Accelerated Access spend on products, net of savings, £m | 152 | **744** |
| | **Net change in spend due to AA, £m** | 52 | **244** |
| *Patients* | QALY gains (from net change in spend) | 1,049 | **5,243** |
| | WSI gains (from QALY gains), £m | 15 | **73** |
| | **Value of QALYs and WSIs gained, £m** | 78 | **388** |
| | QALYs displaced (from net change in spend) | 1,732 | **8,128** |
| | WSIs displaced (from QALYs displaced), £m | 24 | **113** |
| | **Value of QALYs and WSIs displaced, £m** | 128 | **601** |
| *Industry* | **UK profits, £m** | 1.1 | **5** |
| | **UK R&D spillovers, £m** | 0.6 | **3** |
| *Admin* | Accelerated Access Partnership | - | **0.22** |
| | Early Access to Medicines Scheme | - | **17** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 79 | **398** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 128 | **618** |

| | | | |
|---|---|---|---|
| *Net benefit* | *Benefits minus costs, £m* | -49 | **-220** |

For this estimate, the additional spend per medicine and the level of health gain from that spend is unchanged from the "mid" value estimate for option 3. The difference is that the number of QALYS displaced has fallen from 3,465 to 1,732. Consequently the net loss has fallen to £49m per medicines and £220m overall. The NHS would still need to find £244m over 15 years to fund these 5 medicines.

## Running the AAC for 5 years

Extrapolating the above analysis for one cohort of products to 5 cohorts, i.e. AAC is operated for 5 years – then the number of products rises to 25 all of which are medicines with managed access. The total values are shown in the table below. They have been discounted in line with the Green Book.

Figure 14: Impacts of AAC operating over 5 years

| **PRESENT VALUE OF CUMULATIVE IMPACTS (5 year implementation)** | | | |
|---|---|---|---|
| | ***Scenarios*** | | |
| | *Product numbers affected pa* | 5 | **5** |
| | *Total products* | 25 | **25** |
| ***Impacts*** | | | |
| *NHS spend* | Counterfactual spend on products, net of savings, £m | 2,043 | **2,043** |
| | Accelerated Access spend on products, net of savings, £m | 3,332 | **3,332** |
| | **Net change in spend due to AA, £m** | 1,289 | **1,289** |
| *Patients* | QALY gains (from net change in spend) | 29,206 | **29,206** |
| | WSI gains (from QALY gains), £m | 407 | **407** |
| | **Value of QALYs and WSIs gained, £m** | 2,159 | **2,159** |
| | QALYs displaced (from net change in spend) | 42,959 | **42,959** |
| | WSIs displaced (from QALYs displaced), £m | 598 | **598** |
| | **Value of QALYs and WSIs displaced, £m** | 3,176 | **3,176** |
| *Industry* | **UK profits, £m** | 23 | **23** |
| | **UK R&D spillovers, £m** | 12 | **12** |
| *Admin* | Accelerated Access Partnership | - | **1.1** |
| | Early Access to Medicines Scheme | - | **85** |
| *Total Benefits* | *QALYs and WSIs gained, plus industry impacts, £m* | 2,193 | **2,171** |
| *Total Costs* | *Value of QALYs and WSIs displaced, £m* | 3,176 | **3,261** |
| *Net benefit* | *Benefits minus costs, £m* | -983 | **-1,090** |

As with the mid value estimate, the total extra expenditure is £1,289m. The net loss for all five medicines is reduced down to £1,090m by the changes in assumptions about the value of the displaced care.

## Summary of scenario 3

The table below shows the cost benefit and net present value for the scenario of scenario 3

| Option 3 | Cost | Benefit | Net present Value |
|---|---|---|---|
| Mid value estimate | £6,436m | £2,171m | -£4,266m |
| High value estimate | £3,261m | £2,171m | -£1,090m |

The mid value estimate has a net loss of -£4,266m. This is driven by the high price to purchase medicines resulting from the effective ICER of £45,000 per QALY. Relative to NICE's range of acceptable

ICERs, if the medicines displaced NHS care that had an ICER of £30,000 per QALY, the NPV improves to -£1,090m as fewer QALYs are lost. However, there is still a net loss.

### Pressure on NHS medicines spend

As with scenario 2, there is pressure from the proposals on NHS medicines spending although these pressures are much more substantial under scenario 3. If 5 medicines with an uncertain evidence base are selected with associated potential for price increases as set out above, the cost pressure is £225m per year after five years, rising to £425m per year in steady state. Steady state is reached 13 years after AAC is launched; assuming the AAC is permanent.

## Conclusion

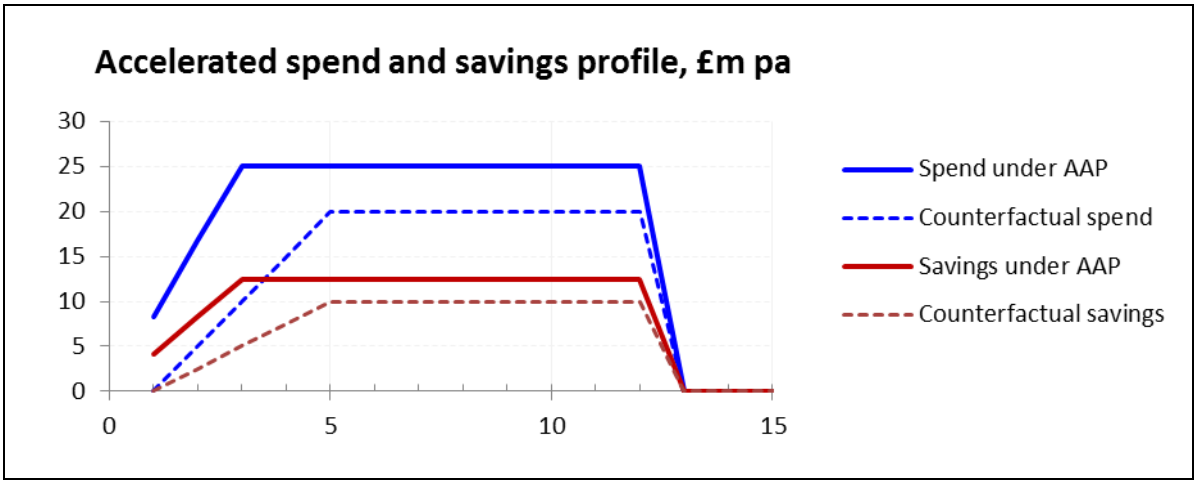
Page 14 sets out the summary of the 3 indicative implementation scenarios, explained in detail on pages 16-28.

While scenario 1 and scenario 2have a large positive net present value benefits, scenario 3 offers a large negative net present value. The policy intention is to achieve a scenario most similar to scenario 2.

Given the range of options for the Government and the Accelerated Access Collaborative to determine the detailed approach to implementation, each of these illustrative scenarios, and a range of others, remain plausible. Without careful regard to cost-effectiveness in implementation, a negative net benefit could ensue. This places an onus on Accelerated Access Collaborative and Government to manage risks, to adopt an approach that will deliver a high net benefit and carefully to monitor the impact of implementation.

## Annex A– Explanation of 5 different technology categories

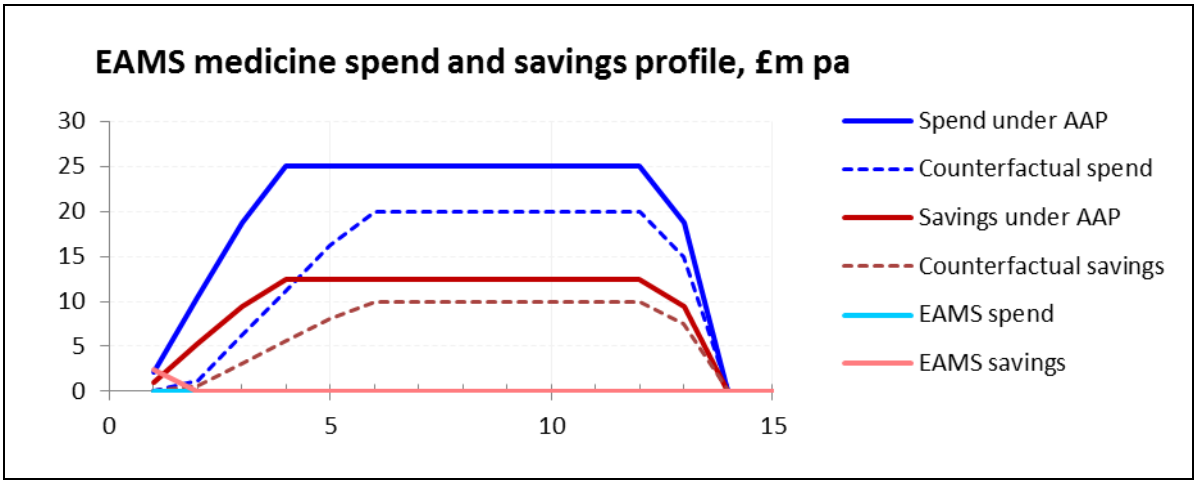
The graphs in this annex show the impact of AAC on the life-cycle for each of the technologies selected, according to the definitions and assumptions set out above, and assuming no price effect. As different conditions apply, each medicine is shown separately. Note that the graphs represent the future lifecycle of all products entering the AAC in a single year.




This graph above shows the expenditure profiles for 1 medicine which has accelerated access only, i.e. it is not subject to EAMS or managed access with conditional approval. The dotted blue line shows the counterfactual expenditure. Expected sales in year 1 are zero, rising to £20m by year 5. Note peak sales are actually £25m for a given product, but there is only 80% chance they will be approved by NICE as these medicines are near the upper end of the NICE ICER range. After 12 years, the value of sales falls as the patent protection period comes to an end.

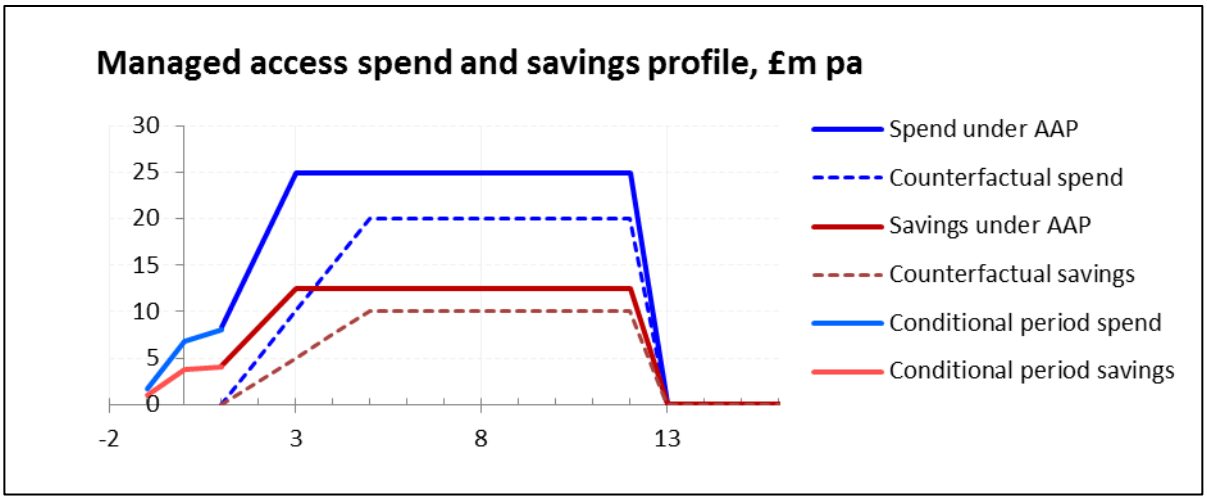
The solid blue line shows spend on the medicine for the accelerated scenario. The level of spend is higher in year 1, uptake is quicker and reaches the peak sales level by year 3. In the steady state, expected sales are also higher because the probability of approval under AAC is 100%. The area between the solid blue line and the dotted blue line represents the increased uptake and additional sales.

The dotted red line and solid red line show the savings to the NHS under the counterfactual scenario and the accelerated scenario respectively. The model assumes the savings are equivalent to 50%[14] of expenditure.

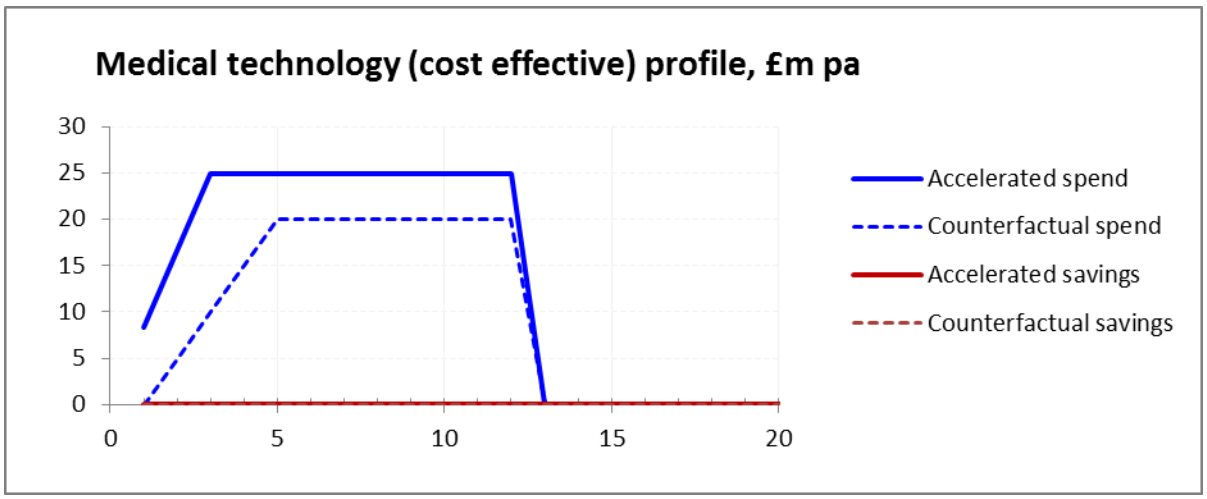



[14] Based on review of published NICE appraisals of comparable medicines – NB, the majority of these savings often come from the alternative treatment, which the new technology replaces.

EAMS means that the medicine is available to patients for 9 months before market authorisation has been granted to collect real world evidence. The modelling assumptions are that it will be available to a reduced cohort of patients (25%); and during this time it will be free of charge to patients[15]. As a result of EAMS the expenditure is £2m lower in the first year.



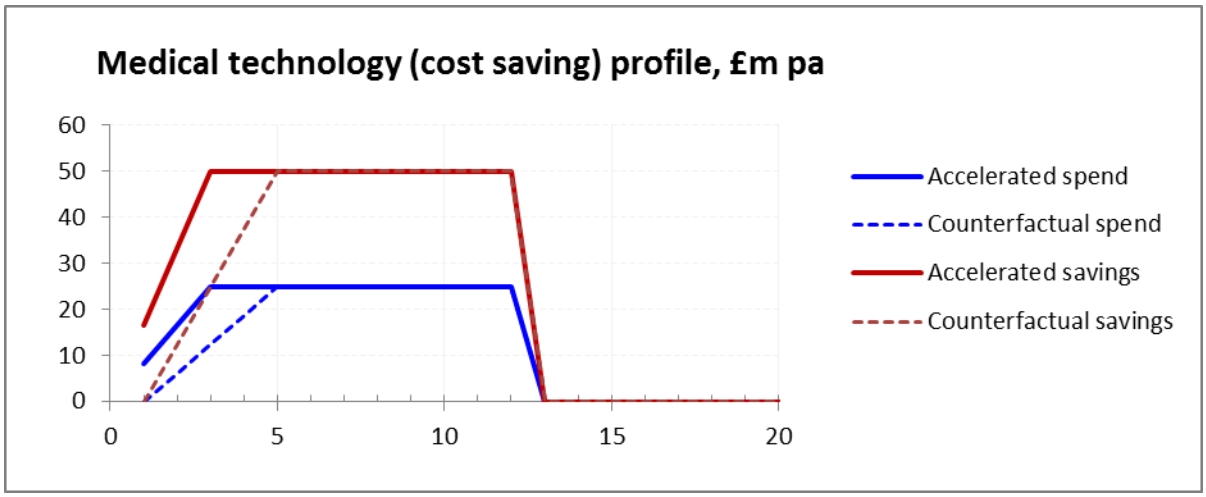

The third medicine would follow the managed access route. Managed access is assumed to last for 2 year from when conditional approval has been granted. Further assumptions are that recruitment of patients is at 30% of the estimated peak patient potential; and that the agreed price during this period is 90% of the proposed list price. Once the medicine has completed the conditional period, the model assumes that it is approved by NICE and becomes available to the NHS at its full price, i.e. the pre-agreed full price.




The gross sales are shown by the blue lines. The solid line shows sales are higher over the life time of the product owing to the accelerated access. As with medicines expected peak sales are also higher owing to products having a 100% probability of approval once accepted by AAC. There are no cash savings to the NHS – the benefit is through generating more health gain.

The next graph shows the profile for a medical technology which is cost saving to the NHS. In other word, it costs the same and delivers the same health gain to patients, but frees up resource elsewhere in the NHS.

[15] In line with current scheme conditions




The assumption, for truly transformative cost saving medical technology products, is that the level of savings can be twice as great as the cost of the product itself. Hence the red line which represents savings is greater than the gross cost blue line for both the AAC scenario and the counterfactual. By bringing forward uptake under AAC, the NHS benefits from greater savings over the lifetime of the product – and the manufacturer benefits from greater sales.

## Annex B – Methodology for the Cost Benefit Model

The model estimates the spend profile for the stylised technologies described in annex A. The total net increase in expenditure per technology in the accelerated scenario is calculated as follows:

*Total net increase = [Gross Spend$_{accel}$ – Savings$_{acel}$] – [Gross Spend$_{count}$ – Savings$_{count}$]*

where

- Gross Spend = price paid by NHS * volume
- Savings = expenditure on next best treatment available to the NHS + efficiency to pathway from new technology

***Benefits***

The benefit to patients from accelerating access of the technology is measured as the health gain to patients in QALYs and the wider societal impacts from that gain health. It is calculated as:

*Total Benefit$_{patients}$ = Benefit$_{health\ gain}$ + Benefit$_{wider\ societal\ impact}$*

where

*Benefit$_{health\ gain}$ = Total net increase * Incremental cost effectiveness ratio (ICER)$_{accel}$*

*Benefit$_{wider\ societal\ impact}$ = Health gain$_{QALYs}$ * Wider societal impact per QALY$_{£}$*

***Costs***

The cost to patients from accelerated is measured as the health in QALYs foregone by displaced care which could have been bought with the resources used to pay for the accelerated use of the chosen technology and the loss of wider societal impacts associated with that care. It is calculated as:

*Total Cost$_{patients}$ = Cost$_{health\ foregone}$ + Cost$_{wider\ societal\ impact}$*

where

*Benefit$_{health\ gain}$ = Total net increase * Incremental cost effectiveness ratio (ICER)$_{displaced\ care}$*

*Cost$_{wider\ societal\ impact}$ = Health foregone$_{QALYs}$ * Wider societal impact per QALY$_{£}$*

The variables used are shown below

| | **Variable** | Med tech (CE) | Med tech (CS) | Medicine (accel) | Medicine (EAMS) | Medicine (MA) |
|---|---|---|---|---|---|---|
| *Counterfactual* | Peak usage (per technology), £m pa | 20 | 20 | 20 | 20 | 20 |
| | Counterfactual Probability of Success | 80% | 80% | 80% | 80% | 80% |
| | Years to peak | 4 | 4 | 4 | 4 | 4 |
| | savings % of spend | 0% | 200% | 50% | 50% | 50% |

| | | | | | | |
|---|---|---|---|---|---|---|
| | savings delay, years | 0 | 0 | 0 | 0 | 0 |
| | savings duration, years | 1 | 1 | 2 | 2 | 2 |
| *Accelerated* | Delay reduction, years | 1 | 1 | 2 | 2 | 2 |
| | Accelerated years to peak | 3 | 3 | 3 | 3 | 3 |
| | Peak usage change, % | 0% | 0% | 0% | 0% | 0% |
| | Price effect, % | 0% | 0% | -9.7% - 0% | -8.6% - 0% | +25% |
| *Product attributes* | Period of sales with patent protection (counterfactual) (years) | 12 | 12 | 12 | 12 | 12 |
| | Period of sales with patent protection (accelerated) (years) | 13 | 13 | 14 | 14 | 14 |
| | Cost / QALY | 10,000 | N/A | 32,000 | 32,000 | 45,000 |
| *EAMS* | EAMS? | NO | NO | NO | YES | NO |
| | Period, years (adds to delay reduction) | N/A | N/A | N/A | 0.75 | N/A |
| | % of peak usage | N/A | N/A | N/A | 25% | N/A |
| | price as % of full | N/A | N/A | N/A | 0.0% | N/A |
| | Probability of success | N/A | N/A | N/A | 100% | N/A |
| *Conditional scheme* | Conditional scheme? | NO | NO | NO | NO | YES |
| | Period, years (subtracts from delay reduction) | N/A | N/A | N/A | 0 | 2 |
| | % of peak usage | N/A | N/A | N/A | 100% | 30% |
| | price as % of full | N/A | N/A | N/A | 100% | 90% |
| | Probability of success (for ac) | N/A | N/A | N/A | 100% | 100% |
| *Policy variables* | Years of policy impact (max 60) | 5 | 5 | 5 | 5 | 5 |
| *Wider Societal Benefits* | £WSIs / QALY gained from product | 11,306 | 11,306 | 11,306 | 11,306 | 13,925 |

***Impacts on businesses***

In addition to patient health the impact assessment also estimates the change to UK business in terms of profits and the economic value of R&D spillover. These are calculated as:

*Total Profits = Total net increase in spend * profit as a proportion of sales*

And

*UK Profits = Total profits * ratio of UK industry to global industry*

*Adjust UK profits = UK profits * income distribution weighting*

*Total R&D Spillover = Total net increase in spend * R&D intensity*

And

*UK R&D Spillover = Total R&D Spillover * ratio of UK industry to global industry*

*Adjusted UK R&D Spillover = UK R&D Spillover * income distribution weighting*

The variables used are

| Variable | |
|---|---|
| Gross profits as proportion of sales | 30% |
| Ratio of UK industry to Global industry (inc through share ownership) (Pharmaceuticals) | 10% |
| Ratio of UK industry to Global industry (inc through share ownership) (med tech) | 25% |
| Income distribution weighting (Green Book) | 0.7 |
| R&D intensity | 36% |

Other variables used in the modelling

| Variable | |
|---|---|
| NHS marginal £cost/QALY (standard assumption) | £15,000 |
| NHS marginal £cost/QALY (alternative assumption) | £30,000 |
| Social value of QALY, £ | £60,000 |
| Discount rate (NHS) | 1.5% |
| Discount rate (private) | 3.5% |
| NHS marginal wider societal impacts £/QALY | 13,925 |