Department of Health & Social Care

NHS Business Services Authority

Part IX of NHS Drug Tariff England and Wales

Enhanced Assessment Framework

08 July 2025

Introduction to the enhanced assessment framework

The Department of Health and Social Care is introducing an enhanced assessment process for products to be listed on Part IX of the Drug Tariff.

- The rationale for the enhanced assessment framework, is that **previous arrangements did not validate claimed product features and benefits** with clinical experts or patient representatives when assessing the evidence, relative efficacy or patient benefit.
- **This document outlines the enhanced assessment framework**, where products must meet pre-qualification criteria, before being scored against quality, social, and price to reach a final score. There is a minimum pass score of 55 out of 100 and products that do not achieve this will not be listed on the tariff.
- This enhanced assessment framework should be used in tandem with the **Part IX application guidance** to complete the **application form which will go live when the notice period is triggered**, when applying for Part IX or applying to renew a Part IX listing.

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Overall scoring approach

This table summarises the overall scoring approach across the enhanced assessment framework.

Prequalification criteria		Quality scoring		Social scoring		Price scoring	
Question	**Pass/Fail**	**Question**	**Points**	**Question**	**Points**	**Product Price**	**Points**
Regulatory	Pass	Value add	10	Circular economy	4	Benchmark	40
Appropriateness to prescribe in primary and community care	Pass	Value add	10	Sustainable packaging	2	+8% higher price	30
Carbon Reduction plan or Net Zero Commitment	Pass	Value add	10	Supply chain resilience	4	+16% higher price	20
Modern Slavery	Pass	Minimum requirement	20			+24% higher price	10
						+32% higher price	0
						More than 32% higher price	Fail
	Pass/Fail	**Maximum Score**	**50**	**Maximum Score**	**10**	**Maximum Score**	**40**
OVERALL PASS SCORE: 55/100							

Sliding scale

Overall Score

All products will receive an overall score as part of their renewal or listing process. The Overall score will be calculated as Quality Score + Social Score + Price Score = Overall score.

Pass Score

The minimum pass score is 55 and the minimum quality score is 20.

Products that are more than 32% higher in price will fail and not be listed, regardless of how they perform on Quality and Social domains.

If they fail, suppliers will have the opportunity to lower prices to remain listed on Part IX, as long as they meet the minimum requirements for quality.

For Quality, suppliers chose a maximum of 3 of 4 quality value add questions as is set out in slides 9-11 in addition to the minimum requirement.

***To note**: All criteria apply to all suppliers, including manufacturers and distributors. Only the company that owns the listing must supply the evidence.*

Prequalification criteria

The following are pre-qualification criteria that must be met for all Part IX applications ahead of quality assessment.

	Criteria	Evidence requirement	Evidence supplied
Product	Regulatory	Evidence meets the relevant medical device regulatory requirements.	Supply of up-to-date CE and/or UKCA certificate MHRA registration number and date registered with MHRA*
	Appropriateness to prescribe in primary and community care	See definition in Annex 1	Written explanation as to how product meets criteria
	Confirmation company is still supplying	Written confirmation in application form	
Supplier	Carbon Reduction Plan or Net Zero commitment	Supplier has the ability to choose either: • A completed Carbon Reduction plan for scope 1, 2, and a subset of scope 3 emissions (those described in the NHS Net Zero supplier roadmap) • Or, a Net Zero commitment. Guidance on both are available here.	Supply of up-to-date Carbon Reduction Plan, or a Net Zero commitment.
	Modern Slavery	Supplier is compliant with the requirements contained within section 54 of the Modern Slavery Act 2015 and associated guidance.	Modern Slavery Statement

**Manufacturers in Northern Ireland should be aware of their registration requirements and be aware of any changes from the MHRA*

Quality evaluation framework

Quality evaluation framework overview

Quality evaluation is comprised of 2 stages:

Stage 1

- **Does the product meet the minimum requirement** (20 points)
  - See minimum requirement evidence breakdown, next slide (slide 8)
  - See specific minimum requirements for continuous glucose monitors (Detection sensors, interstitial fluid for glucose), blood glucose testing strips, ketone testing strips and lancets and insulin pens, slide 26-29.

Stage 2

- The applicant can **choose to submit a maximum of three value add criteria.** With a maximum of 10 points for one criterion, 20 points for two, or 30 points for three value add criteria. The value add criteria (detailed on slides 9-12) are:
  - Product effectiveness
  - Supporting self-care
  - Supporting system savings
  - Reducing inequalities
- An applicant can choose not to submit any value add criteria but will not be awarded more than 20 points on quality

Quality Scoring Framework		
Quality scoring criteria		**Score**
Stage 2 value add criteria		Score
Meets the minimum requirement for category and offers **three value add criteria**		Up to 50
Meets the minimum requirement for category and offers **two value add criteria**		Up to 40
Meets the minimum requirement for category and offers **one value add criteria**		Up to 30
Stage 1 minimum requirement criteria	Evaluation criteria	Score
Meets the **minimum requirement** for category.	• Appropriate for chosen category, as agreed by independent advisory panel. • Meets minimum evidence requirements, for the application type.	20
Criteria	Evaluation criteria	Score
Does not meet the requirement for the category.	• Lacking safety and quality mark or certification, value add element will not be scored. • Not appropriate for category. • Does not meet requirements - at discretion of independent advisory panel, if significant concerns.	Fail

Quality evaluation framework - *minimum requirement - 20 points*

Type of Application	Criteria	Evidence Requirement*	Scoring
New application for new type of product ***i.e. where no comparable products currently listed on the tariff***	• Provide evidence of effectiveness of the product, compared to the current standard of care. • Provide evidence demonstrating the product functions as stated.	• Clinical evidence/ real-world evidence • Evidence should be a minimum of 2+ per levels of evidence, annex 2	Pass/Fail
Me too application – new application for existing type of product ***i.e. where there is an existing comparable product in Part IX of the tariff***	• Provide evidence product is as effective as existing products in the cluster.	• Clinical evidence is not generally required if a similar product is already included in the Drug Tariff. • Evidence that the product is the same as the comparable products.	Pass/Fail
Line extensions	• Provide evidence product is as effective as the current listing that new line is being added to.	• Clinical evidence is not generally required if a similar product is already included in the Drug Tariff. • Evidence that the product is the same as the current listing that new line is being added to.	Pass/Fail
Renewals of products already listed on Tariff	• Not Applicable –The requirements are the prequalification criteria**	• Not applicable	Pass/Fail

** These are intended as guidelines, if the supplier can issue other credible evidence to support contribution to this theme this will be evaluated if a clear rationale is provided.*
***If the panel has concerns about existing products on Part IX of the Drug Tariff, they can request further evidence from the supplier.*
Note: *See specific minimum requirements for continuous glucose monitors (Detection sensors, interstitial fluid for glucose), blood glucose testing strips, ketone testing strips and lancets– Annex 3, 4, 5. Devices with apps should meet Digital Technology Assessment Criteria (DTAC) requirements.*

Quality evaluation framework - value add
Product effectiveness - *10 points*

How does your product demonstrate product effectiveness and deliver predictable, consistent outcomes, above and beyond the minimum requirement?			
Prompts*	Evidence*	Scoring	Points
• What evidence supports the product efficacy of your product above and beyond the minimum requirement? • How does your product improve patient outcomes compared to alternatives?	• Clinical or real-world evidence. • Performance metrics showing measurable patient benefits.	Good demonstration. The evidence robustly demonstrates product effectiveness beyond minimum requirements and clear, measurable benefits. Supported by evidence: Clinical evidence levels 3, 2-, 2++, 2+, 1++, 1+, 1- as per Evidence Grading** guidance, annex 2. The panel reserves the right to exclude if deemed unsuitable.	Good (10 points)
		Satisfactory demonstration of product effectiveness beyond the minimum requirements. Supported by evidence: Clinical evidence levels 3, 2-, 2++, 2+, 1++, 1+, 1- as per Evidence Grading** guidance, annex 2. The panel reserves the right to exclude Level 2- or Level 3 if deemed unsuitable.	Satisfactory (5 points)
		Poor demonstration. There is little, weak or unclear evidence on improved product effectiveness.	Poor (0 points)

**These are intended as guidelines and are not exhaustive so if the supplier can issue other credible evidence to support contribution to this theme this will be evaluated if a clear rationale is provided.*
*** See Annex 1.*

Quality evaluation framework - value add
Supporting self-care - *10 points*

How does your product enable patients to manage their own care effectively and reduce reliance on clinical intervention?			
Prompts*	Evidence*	Scoring	**Points**
• Does the product design support ease of use for patients or caregivers? • What resources (e.g., guides, apps) are available to help patients use the product? • What resources are available to help patients use the product correctly in between clinician visits?	• User manuals and training resources. • Case studies showing reduced reliance on healthcare providers. • Patient feedback or satisfaction surveys.	Good demonstration. The evidence robustly demonstrates improved self-care enablement, with clear patient benefits and evidence of reduced reliance on clinical intervention.	Good (10 points)
		Satisfactory demonstration. There is evidence of improved self-care enablement.	Satisfactory (5 points)
		Poor demonstration. There is little, weak or unclear evidence on improved self-care enablement.	Poor (0 points)

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Quality evaluation framework - value add
Supporting system savings - *10 points*

How does your product deliver value for money through lifecycle cost savings or reduced healthcare utilisation?			
Prompts*	Evidence*	Scoring	**Points**
• What is the total cost of ownership for your product (e.g., lifespan, replacement frequency)? • How does your product reduce healthcare costs (e.g., fewer hospital visits, shorter stays)? • Does the product require less frequent replacement or maintenance compared to alternatives?	• Cost-benefit analysis showing long-term savings. • Evidence of reduced healthcare utilisation (e.g., fewer interventions or hospital stays). • Lifecycle assessments demonstrating durability or reduced replacement costs.	Good demonstration. The evidence robustly demonstrates increased system savings.	Good (10 points)
		Satisfactory demonstration. There is evidence of increased system savings.	Satisfactory (5 points)
		Poor demonstration. There is little, weak or unclear evidence on system savings.	Poor (0 points)

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Quality evaluation framework - value add
Reducing inequalities - *10 points*

Detail how the use of your product may reduce inequalities in access, experience or outcomes within the target pathway?			
Prompts*	Evidence*	Scoring	**Points**
• How is the product designed to accommodate diverse needs (e.g., disabilities, comorbidities, cultural differences)?	• Case studies addressing access/usage issues for specific populations or evidence of addressing bias	Good demonstration. Evidence robustly demonstrates that the product is designed to address health inequalities, and evidence of patient benefits.	Good (10 points)
		Satisfactory demonstration. Evidence demonstrates that the product is designed to address health inequalities.	Satisfactory (5 points)
		Poor demonstration. There is little, weak or unclear evidence the product is designed to accommodate diverse needs.	Poor (0 points)

** These are intended as guidelines and are not exhaustive so if the supplier can issue other credible evidence to support contribution to this theme this will be evaluated if a clear rationale is provided.*

Value add - Quality attribute prompts by category

- The following two slides are examples of quality considerations that may be relevant to demonstrate quality value add.
- The suggestions provided are not meant to be a prescriptive or exhaustive list of quality attributes and measures.

Value add – Example Quality attribute prompts by category

	Wound and skin care	Gastrointestinal care products	Urological care products	Sexual, reproductive and pelvic health products	Point of care testing and hypodermic equipment products	Oral, dental, ear, eye and nasal care products	Respiratory Tract and airway management products	Lymphoedema, support and therapeutics products
Product Effectiveness	• Material composition should be clear • Suitability for those with allergies	• Fit and comfort of devices for long-term use • Suitability for those with allergies	• Skin compatibility and minimising irritation • Suitability for those with allergies	• Suitability for those with allergies	• Reliable and stable connectivity (where applicable) • Connectivity alerts • Rapid result turnaround times • Predictive alerts (Continuous Glucose Monitor)	• Presence of topical alcohol should be clearly marked • Suitability for those with allergies • Minimal negative side effects e.g. tooth decay	• Suitability for those with allergies • Anti-static properties clearly indicated (where static risk identified)	• Compression levels clearly indicated • Suitability for those with allergies • Easy application and adjustment to ensure correct fit
Supporting Self-Care	• Packaging Design (e.g. ease of opening) • User instructions for self-application and good concordance of use, including digital resources	• Ease of use for patients or carers • Reusable products options where clinically appropriate	• Features supporting adherence to treatment regime	• Post-sale support	• Continuous Glucose Monitors: compatibility with apps for self-monitoring • Post sale support on evenings/weekends • Insulin delivery: dosage tracking support, dosing flexibility (e.g. half-unit increments) • Small, discrete and pain-free devices	• Clear and concise user guidance for safe application	• Simple and clear instructions for users to follow • Clear labelling to distinguish inhaler types or mask sizes • Post-sale support	• Instructional materials for correct fitting and use • Clear instructions and compression level indication on label/packaging • Video guides for applying complex garments or wraps

To note, value add criteria must be beyond the minimum requirements for the product. Additionally, these value add criteria are examples and there will be many other examples of value add attributes that meet the criteria.

Value add – Example Quality attribute prompts by category

	Wound and skin care	Gastrointestinal care products	Urological care products	Sexual, reproductive and pelvic health products	Point of care testing and insulin delivery products	Oral, dental, ear, eye and nasal care products	Respiratory Tract and airway management products	Lymphoedema, support and therapeutics products
Supporting System Savings	• Extended wear times • Unit issue efficiency (e.g. smaller packaging sizes) • Longer shelf life	• Durability, supporting intended length of use • Longer shelf life	• Reusable product options where clinically appropriate • Durability, supporting intended length of use	• Durability, supporting intended length of use • Reusable or recyclable components where possible	• Longer shelf life • Reduced need for frequent calibration or maintenance • Integration with hospital systems (e.g. automatic data upload)	• Durable materials supporting intended length of use • Reusable or recyclable components where possible	• Durable materials supporting intended length of use • Reusable options (e.g., inhaler spacers)	• Durable materials supporting intended length of use • Reusable components where feasible (e.g., compression pumps)
Reducing Health Inequalities	• Visible dressings (outer layer) with options for different skin tones • Features supporting use across various dexterity levels	• Features supporting use across various dexterity levels • Options for different skin tones • Discrete design (odourless, aesthetic and fit)	• Features supporting use across various dexterity levels	• Features supporting use across various dexterity levels • Adjustable sizing/ fit	• Features to support use across user abilities and backgrounds (e.g. audio alert/ read out capability for those with visual impairment) • CGM indication for different cohorts	• Features supporting use across various dexterity levels • Culturally appropriate product designs (e.g., halal/kosher certification for consumables where applicable)	• Features supporting use across various dexterity levels	• Features supporting use across various dexterity levels • Availability of multiple sizes and styles to accommodate different ages/ weights and ethnic groups

To note, value add criteria must be beyond the minimum requirements for the product. Additionally, these value add criteria are examples and there will be many other examples of value add attributes that meet the criteria.

Social evaluation framework

Social evaluation framework - executive summary

Context
Social is a newly assessed element included in the enhanced assessment framework. The Government has an opportunity and responsibility to maximise benefits effectively and comprehensively through its commercial activity.

Scoring
There are three criteria under social that a supplier can apply with. These are:

- Circular economy (4 points maximum)
- Sustainable packaging (2 points maximum)
- Supply chain resilience (4 points maximum)

The following slides provide further detail on how questions will be assessed and scored. All social criteria apply to both manufacturers and distributors, whoever owns the Part IX application/ listing.

Social scoring	
Question	**Max score (pts)**
Circular economy	4
Sustainable packaging	2
Supply chain resilience	4
Total	**10**

Social evaluation framework – *circular economy*

How does your product support a circular economy? (Does it preserve its value after use, through reuse, remanufacture and/or recycling?)			
Prompts*	**Evidence***	**Scoring**	**Points**
• Specify how many times your product can be safely reused before disposal • Describe to what extent your product, or modular components of the product, can easily be recycled through domestic waste streams. • Detail any take-back, remanufacture or recycling schemes you operate, including partnerships with waste management providers • Provide data on what proportion of your product is made from recycled materials, and any other steps taken to reduce use of virgin raw materials or resources in production • Explain how your product reduces the volume of products required or disposed of in the course of the patient's treatment through modular design or a longer use-life than equivalent products • Detail what guidance is provided alongside your product on correct disposal.	• Lifecycle assessments (LCAs) demonstrating the environmental benefits of the product's circularity • Certifications for material recyclability or biodegradability (e.g., ISO 14021) • Documentation of take-back schemes, including data on waste reduction or recycling rates. • Case studies or examples of how the product contributes to reducing waste in practice	Demonstrates strong support for a circular economy through reuse, remanufacture, recycling, reduction or a combination. The product demonstrates equal or-significantly greater circular economy support when compared with the best equivalent products on the market. Provides clear disposal guidance that maximises recyclability.	Good (4 Points)
		Demonstrates some support for a circular economy through reuse, remanufacture, recycling, reduction or a combination, but to a limited extent. The product demonstrates equal but not significantly greater circular economy support when compared with the majority of equivalent products on the market. Provides clear disposal guidance that maximises recyclability.	Satisfactory (2 Points)
		No demonstration that the product supports a circular economy. Or the product is significantly less supportive of a circular economy when compared with the majority of equivalent products on the market.	Poor (0 Points)

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Social evaluation framework – *sustainable packaging*

How have you minimised the environmental impact of your product's packaging?			
Prompts*	**Evidence***	**Scoring**	**Points**
• Explain how you have minimised the amount of packaging provided with the product, including secondary packaging • Specify how much of the packaging can easily be recycled through domestic waste streams and explain the presence of any non-recyclable packaging • Specify what proportion of the packaging uses recycled materials	• Breakdown of recyclability (% of packaging recyclable via standard household waste vs. specialist facilities) • Data on % recycled content (post-consumer recycled materials) • Lifecycle analysis or carbon footprint assessment of packaging • Compliance with NHS sustainability goals, UK Plastics Packaging Tax, and relevant ISO standards (ISO 14001, FSC-certified materials)	Demonstrates strong support for the NHS Supply Chain Packaging Programme and Net Zero commitments. Uses minimal, lightweight, and recyclable packaging. Packaging is widely recyclable through household waste streams or closed-loop systems. No unnecessary plastic or non-recyclable materials unless clinically essential, with clear justification.	Good (2 Points)
		Demonstrates some support for NHS sustainability targets. Some efforts made to reduce packaging waste, but non-recyclable components are present without clear alternatives. Recyclability is limited to specialist facilities. Some commitment to circular economy principles, but evidence is inconsistent or incomplete.	Satisfactory (1 Points)
		Poor demonstration. There is little, weak or unclear evidence the product is designed to ensure packaging is sustainable.	Poor (0 Points)

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Social evaluation framework – *supply chain resilience*

How do you ensure a resilient and continuous supply of your product, withstanding supply shocks and disruptions?			
Prompts*	**Evidence***	**Scoring**	**Points**
• Outline your approach to monitoring and mitigating risk in the supply chain, including sourcing diversification, inventory management, contingency planning, and onshoring or alternative manufacturing sites. • Provide examples of measures taken to address specific threats (e.g., geopolitical shocks, manufacturing delays, demand surges and raw materials shortages). • Explain to what extent your product is interoperable with other manufacturers' products and consumables. • Explain what mitigations are in place to reduce the risk of technology obsolescence.	• Risk assessments or business continuity plans detailing contingency measures for supply chain disruptions. • Data on inventory levels, sourcing diversification, and supplier reliability, UK-based or alternative manufacturing sites. • Case studies demonstrating successful mitigation of supply chain disruptions or capacity scaling during demand spikes. • Certifications or audits related to supply chain standards (e.g., ISO 22301 for Business Continuity Management).	Demonstrates strong supply resilience. Evidence for a robust, proactive approach with comprehensive risk monitoring, sourcing diversification, contingency planning, and inventory management. Provides strong evidence of successful mitigation strategies and ensures high interoperability with other products. Clear measures to prevent technology obsolescence, supported for example by risk assessments, supplier data or case studies.	Good (4 Points)
		Demonstrates some mitigation strategies, but these are not fully tested or consistently applied. Addresses most important aspects but lacks depth in risk management, contingency planning, or supplier diversification. Product has some interoperability, and technology obsolescence risks are acknowledged but not well-documented. Evidence is partial or inconsistent, with gaps in risk assessments or case studies.	Satisfactory (2 Points)
		Poor demonstration. There is little, weak or unclear evidence of strong supply resilience.	Poor (0 Points)

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Price evaluation

Price scoring

Price scoring

The pricing score will range from 0-40, with 40 being allocated to the benchmark price in a cluster.

The deduction rate has been set at 1.25. Therefore, for every 1% higher than the benchmark price 1.25 points are deducted.

Products that are deducted more than 40 points on Price will fail the enhanced assessment framework, regardless of how they perform on Quality and Social domains.

The benchmark

The Benchmark will be set to the lowest priced product in a comparable cluster, which accounts for at least 5% of the clusters prescription volume that meet the minimum requirements for quality. Other criteria may be considered for cases where a lower threshold on either volume or total cost share may be more appropriate, and these cases will be decided by NHS BSA.

Price checks

Each benchmark price will be reviewed by NHS Prescription Services to ensure that it is appropriate. They may request additional information from suppliers to understand whether a price is appropriate. NHS Prescriptions Services can manually set the benchmark price if they believe the resultant benchmark price from the methodology is inappropriate. For example, it may be considered that the price has increased too much from the current listed price, the price may be artificially low, or the product price is not reflective of the cluster. See Part IX Application Guidance 2.0 for further information.

Price Scoring		
Product Price	**Deduction (pts)**	**Max score (pts)**
Benchmark	0	40
+8% higher price	10	30
+16% higher price	20	20
+24% higher price	30	10
+32% higher price	40	0
>32% higher price	Fail	Fail
Total		**40**

Annexes

Annex 1 – Definition for ‘appropriateness to prescribe in primary and community care’

- Some appliances may be appropriate for use in the community but not eligible for prescribing on an FP10 (standard prescribing form used in England) and a listing on Part IX will be rejected.
  - **Could it be loaned** - An example of this is when it would be more appropriate to loan a medical device to a patient rather than prescribing it. Prescribing a product makes it the patient’s property. The supply on prescription may not be the most cost-effective route of making the appliance available in the NHS, and NHS Prescription Services may challenge this proposed route of supply, if they think this route of supply would be too costly.
  - **Is the pack size appropriate** - Similar considerations may apply where products which are supplied in pack sizes are not appropriate for individual use as a patient may not have the space at home to store products for instance.
  - **Not for social care products** - Prescribed items allowable on an FP10 should be for the treatment of a medical condition – which can include diagnosis and prevention. This does not include items that could be considered more appropriate for the social care of an individual e.g. incontinence and sanitary pads, modified cutlery or crockery, or drinking vessels, wheelchairs and walking sticks etc.
  - **Self administered/ no enhanced training required -** Appliances considered appropriate for prescribing by GPs and other prescribers will usually be for self-administration by the patient, perhaps with the help of a carer. Some appliances may need to be administered by a doctor or other health professional. These products should not require enhanced training of the doctor or health professional specifically in their use. If a product was only suitable for use in a hospital setting it would not satisfy the criteria.
- This list is not intended to be exhaustive, and NHS Prescription Services will advise on suitability, and inform the applicant of the final decision.
- The above consideration is only likely to be necessary when similar products have not been previously listed in Part IX. If a similar product is already listed in Part IX, the criterion would generally be extended to a similar product, unless clinical practice has moved on and it is no longer a product the panel think suitable for prescribing on the NHS.

Annex 2 – Levels of evidence

Levels of evidence	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1−	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2−	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Case reports, case series
4	Expert opinion

RCTs = randomised control trials

Annex 3 - Minimum requirements
Continuous glucose monitors – Page 1
(Glucose interstitial fluid detection sensors)

Question	Outcome
Is the CGM system currently available in the UK? (Yes/No)	Yes = Pass, No = Fail
Please provide a copy of the clinical data available	
Does the indicated age range match the subject age range tested in the clinical data? (Yes/No)	Yes = Pass, No = Fail
Does the clinical data show minimum paired readings in high and low ranges for the populations tested (which includes 70-75% diabetes) with a. At least 8% <4.4 mmol/L - performance metrics for CLSI AND b. At least 5% >16.7 mmol/L - performance metrics for CLSI? (Yes/No)	Yes = Pass, No = Fail
If the sensor, transmitter or sensor/transmitter if combined fails, do you supply a free of charge replacement? (Yes/No)	Yes = Pass, No = Fail
If the transmitter is a separate component to the sensor, what is the transmitter shelf life (unopened)? (Months)	≥ 12 months = Pass < 12 months = Fail Not applicable = Pass
What is the sensor (or sensor/transmitter if combined) shelf-life (unopened)? (Months)	≥ 12 months = Pass < 12 months = Fail
If the CGM system requires the use of an app, are there any charges for using the app? (Yes/No/Not applicable as app not required)	Yes =Fail, No = Pass Not applicable = Pass

Annex 3 - Minimum requirements
Continuous glucose monitors – Page 2
(Glucose interstitial fluid detection sensors)

Question	Outcome
Can the CGM system be used with a handset/reader rather than a smartphone? (Yes/No)	Yes = Pass, No = Fail
Is the handset/reader provided free of charge? (Yes/No)	Yes = Pass, No = Fail
Does the CGM system measure only in mmol/l units and cannot be changed? (Yes/No)	Yes = Pass, No = Fail
Is the user able to delete readings from the meter memory? (Yes/No)	Yes = Fail, No = Pass
Does the CGM system allow data sharing with someone else who is a healthcare professional or carer? (Yes/No)	Yes = Pass, No = Fail
Is there a warning for a high result? (Yes/No)	Yes = Pass, No = Fail
Is there a warning for a low result? (Yes/No)	Yes = Pass, No = Fail
Is the sensor (or sensor/transmitter if combined) waterproof? (Yes/No)	Yes = Pass, No = Fail
Please state waterproof level e.g. IPX7, IPX8 etc	IPX7 and above = Pass IPX6 and below = Fail
Does the company have a UK presence for technical support by freephone telephone and other communication methods e.g. internet?	Yes = Pass, No = Fail
Is support material for healthcare professionals and service users provided free of charge?	Yes = Pass, No = Fail
Is the app linked to the device compliant with UK GDPR	Yes = Pass, No = Fail

Annex 4 - Minimum requirements
Chemical reagents: Blood glucose strips and ketone strips

Blood glucose strips for standard meter/ketone meter	Rationale	Scoring
Compliance with ISO Standard ISO 15197:2015	All blood glucose strips need to comply with ISO standards. However compliance with ISO 15197:2013 confers compliance with 2015 so this would be in.	Pass/Fail
No known plans for blood glucose strips to be discontinued/or the meter has already been discontinued	To ensure that service user is able to obtain the blood glucose strips and continue to use existing meter	Pass/Fail
Strip expiry date >12months if container not opened	To minimise wastage through expired strips	Pass/Fail
Warning for sample under-fill detection	Considered essential that meters are able to determine if there is sample under-fill detection on the blood glucose strip	Pass/Fail

Ketone strips for ketone meter	Rationale	Scoring
No known plans for blood ketone strips to be discontinued	To ensure that service user is able to obtain the ketone testing strips and continue to use existing meter	Pass/Fail
Strip expiry date ≥12 months if container not opened	To minimise wastage through expired strips	Pass/Fail
Warning for sample under-fill detection	Considered essential that meters are able to determine if there is sample under-fill detection.	Pass/Fail
Range of ketones measured is at least 0.1-8.0mmol/l	To ensure meter is able to detect wide range of ketone levels	Pass/Fail

Annex 5 – Minimum requirements
Lancets and Insulin pen needles

Lancets for Lancing devices	Rationale	Scoring
Lancets are single use only	Infection control	Pass/Fail
No known plans for lancets to be discontinued	To ensure that service user is able to obtain the lancets to use in the lancing device	Pass/Fail

Insulin pen needles	Scoring
Are there any known plans to discontinue this product? (Yes/No)	No = Pass Yes = Fail
Is this a safety insulin pen needle? (Yes/No)	No = Pass Yes = Fail
Are the insulin pen needles single or multi-use? (Single/Multi)	Single use = Pass Multiple use = Fail
Is support material or training for healthcare professionals and service users provided free of charge? (Yes/No)	Yes = Pass No = Fail
Do you provide technical support by UK based freephone telephone and other communication methods e.g. internet? (Yes/No)	Yes = Pass No = Fail