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Who Pays for a First-in-Class Stem Cell Therapy

The commissioning, funding, policy and finance map behind National Market Access Commercialisation covering ten to eleven designated specialist treatment centres.

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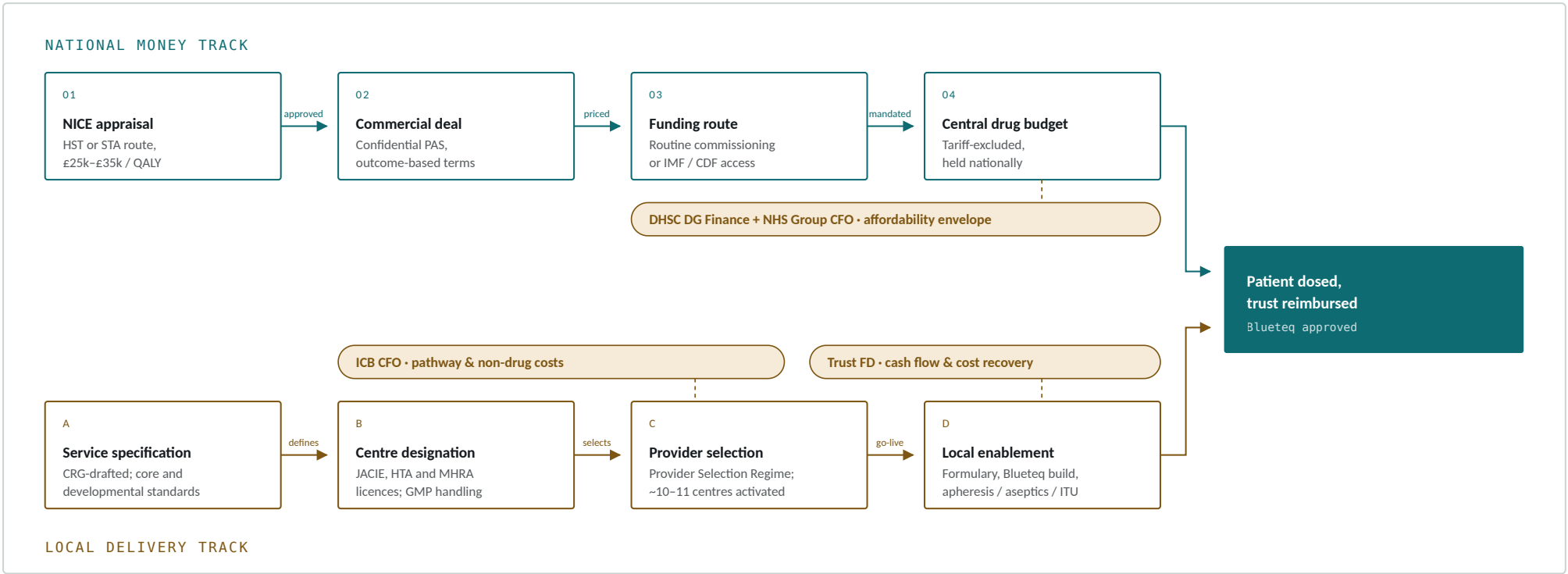
Product · ATMP, one-shot
Footprint · ~10–11 centres
Drug budget · held nationally
Pathway cost · held locally

Two tracks, one gate

A NICE recommendation funds the molecule. It does not fund the apheresis slot, the aseptic suite or the ITU bed — and it does not designate a centre. Both tracks have to finish before a patient is dosed, and they are gated by different people.



Both tracks must complete. The teal track is national and largely out of local hands; the brass track is where commercialisation actually happens. The rounded brass bars are the finance sign-offs — note that none of them sit on the NICE decision, and two of the three sit on the delivery track.

What happens at each stage

NATIONAL MONEY TRACK

01 Marketing authorisation and NICE

Highly Specialised Technologies route for very small populations, otherwise a standard appraisal with the severity modifier. From April 2026 the threshold sits at **£25,000–£35,000 per QALY**, up roughly 25% and the first movement in two decades.

02 Commercial agreement

Confidential patient access scheme under the NHS commercial framework for new medicines. One-shot therapies frequently take outcome-based or staged-payment terms, which changes how a trust books the cost.

03 Routine commissioning or managed access

Where evidence is immature — the norm for first-in-class cell therapy — the Innovative Medicines Fund (non-cancer) or Cancer Drugs Fund carries it with a data collection agreement and a dated exit review. Funding mandate is 90 days unless NICE agrees a variation for service readiness, which ATMPs usually get.

04 Central high-cost drug budget

NHS England remains accountable commissioner for all specialised services. High-cost drugs are excluded from ICB allocations and held centrally, and the product is tariff-excluded under the 2026/27 NHS Payment Scheme — paid as pass-through, gated patient by patient through a Blueteq form.

LOCAL DELIVERY TRACK

A Service specification

Drafted through the relevant Clinical Reference Group, setting core standards every funded provider must meet and developmental standards that stretch them. This document decides what a centre has to be able to do.

B Centre designation

Why the footprint is ten or eleven and not fifty: JACIE accreditation, HTA and MHRA licensing, GMP-compliant cell handling and cryostorage, apheresis capability and ITU escalation. Capability, not geography, sets the map.

C Provider selection and tendering

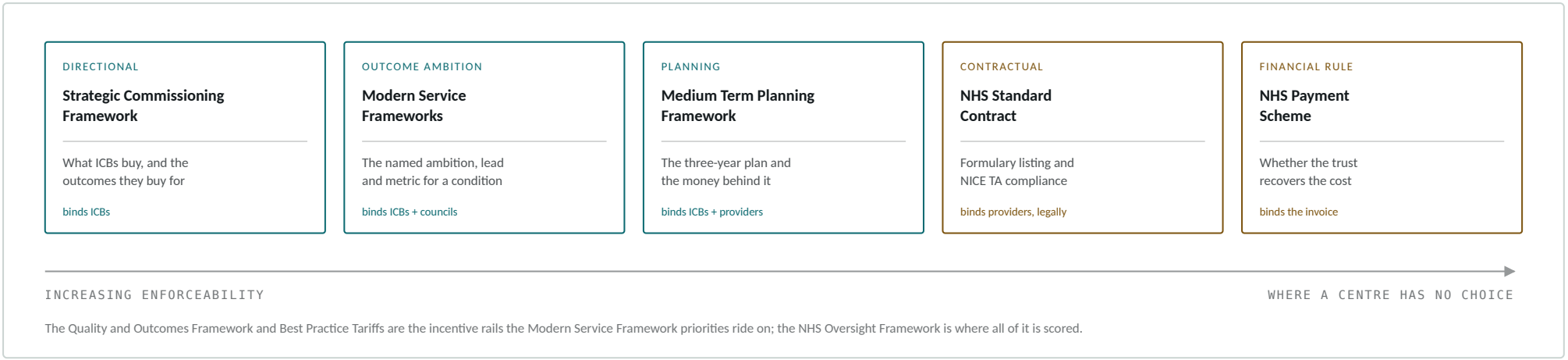
Service provision runs through the Provider Selection Regime. Product supply runs separately through national frameworks — Medicines Procurement and Supply Chain, formerly the CMU — and regional hubs such as LPP, NHS Commercial Solutions and the East of England hub. For a single-source ATMP this is usually direct award, but the paperwork still gates the first dose.

D Local enablement

Trust Drug & Therapeutics Committee, Area Prescribing Committee and Regional Medicines Optimisation Committee sign-off; Blueteq form configured and tested; workup, apheresis, aseptics, bed and CNS capacity actually booked. This is where months are lost.

The policy instruments that govern it

Six documents set the rules National Market Access Commercialisation works inside. They are not equal: two describe intent, two set plans and money, and two can actually compel a trust to act. Knowing which is which is the difference between a persuasive conversation and an enforceable one.



Argue at the right level. A conversation about population outcomes belongs on the left of this line; a stalled formulary listing or an unrecovered drug cost belongs on the right, where a clause or a pricing rule settles it.

Strategic Commissioning Framework

DIRECTIONAL

Published November 2025. Turns ICBs into strategic commissioners on a four-stage cycle: integrated needs assessment from linked person-level data (March 2026), five-year population health improvement plans (January 2026), resource allocation through contracting and procurement, then evaluation. It explicitly encourages risk-sharing arrangements, best practice tariffs and year-of-care payments, and covers all commissioned services including specialised care.

> **So what:** the buying question stops being "can this centre deliver it" and becomes "what does this do for an identified cohort". It also gives you the vocabulary — and the official blessing — for an outcomes-based deal, which is the natural shape for a one-shot therapy. Bring cohort size, unmet need and inequality data, not just efficacy.

Modern Service Frameworks

OUTCOME AMBITION

The 10 Year Health Plan's successor to the old National Service Frameworks. Each sets a national outcome ambition for a major condition, names the evidence-based interventions to get there, attaches standards and measures, and defines who is accountable — with ICBs naming a clinical lead and variation between best and worst performers tracked as a metric in its own right. Cardiovascular disease was first (July 2026), sepsis followed, with severe mental illness and frailty/dementia expected. Priorities are already wired into 2026/27 incentive schemes including QOF and acute Best Practice Tariffs.

> **So what:** if a framework covers your therapy area, it is the strongest narrative hook available — a named accountable lead, a three-year target and a 10-year ambition you can attach the therapy to. If none does, you are competing for attention against conditions that have one, and the honest move is to argue your way into the nearest framework rather than around it.

Medium Term Planning Framework 2026/27–2028/29

PLANNING

Ends annual planning in favour of three-year plans against a multi-year settlement — revenue rising ~3% in real terms to £226bn by 2028/29 — with balanced budgets and no deficit support by 2028/29 and a minimum 2% annual productivity requirement. It mandates adoption of the Modern Service Frameworks, delivery against the NHS Genomic Medicine Service specification from April 2026, and a **Single National Formulary** within two years (categorisation from December 2026 in 13 early-adopter ICBs, first therapy areas live July 2027). Named 2026/27 medicines efficiency targets include DOACs, SGLT-2 and wet AMD pathways.

> **So what:** three things. Your account plan should be a three-year plan, because that is now the unit systems think in and there is a real window to get into one. The no-deficit rule and the 2% productivity ask are why the trust finance conversation is about cash, not value. And if eligibility for your therapy is genomically defined, the April 2026 genomics obligation is a lever, not a barrier.

NHS Standard Contract 2026/27

CONTRACTUAL

The legally binding agreement between commissioner and provider. **SC2.1.6** requires providers to comply with NICE Technology Appraisals and have regard to other NICE guidance. **SC27** requires published formularies that reflect all positive NICE TAs and that recommended treatments are made available. **SC20** is the Service Development and Improvement Plan — the named vehicle for a dated, agreed service change. For 2026/27 the balance tilts toward commissioners: up to 10% of monthly payment can be withheld where a provider fails to engage in contract management within 10 operational days, indicative activity plans can be set unilaterally, and the independent escalation panel is abolished.

> **So what:** this is your hardest lever. "It isn't on our formulary yet" is a contractual issue under SC27, not a preference — and an SDIP under SC20 is how you convert a designated centre's good intentions into a dated activation plan with a commissioner's name on it. Because power has shifted toward commissioners this year, the ICB conversation now moves a reluctant trust further than it did.

NHS Payment Scheme 2026/27

FINANCIAL RULE

Sets the prices and pricing rules. High-cost drugs, devices and listed procedures are unbundled and excluded from prices and paid for separately, with the agreed price adjusted for any cost already captured in a unit price. For 2026/27 a tranche of drugs commonly delivered as homecare came off the exclusion list and into prices, and legacy routinely-commissioned policies for drugs now in tariff took effect from April 2026.

> **So what:** exclusion status decides whether the centre recovers your product's cost or absorbs it, and it is revisited every year — confirm it annually and tell your centres before they find out from a rejected claim. It also fuels a recurring argument: where surrounding activity sits in tariff, commissioners treat the pathway as already paid for, even when the aseptic and ITU capacity it needs plainly is not.

Quality and Outcomes Framework 2026/27

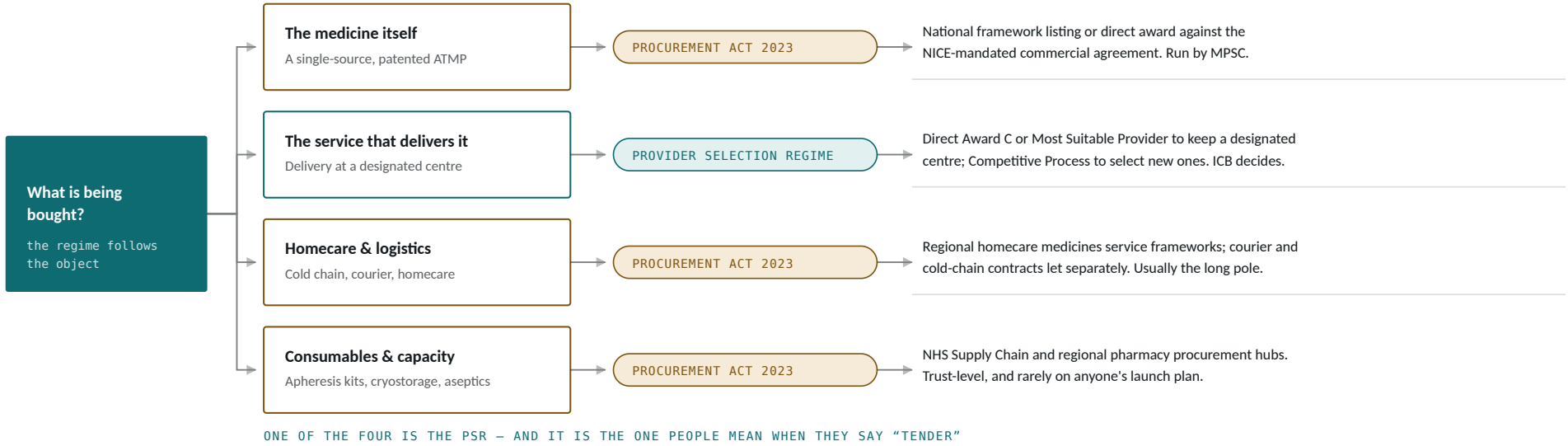
PRIMARY CARE INCENTIVE

The GP contract's incentive scheme, with 2026/27 guidance aligned to Modern Service Framework priorities. It has no direct bearing on a tertiary treating centre — but QOF registers and indicators are how undiagnosed and under-treated patients get found and coded in primary care.

> **So what:** for a therapy whose limiting factor is finding eligible patients rather than treating them, QOF is the upstream tap. Worth distinguishing in an interview: QOF incentivises GPs, while the outcomes ICBs themselves are held to sit in the Strategic Commissioning Framework and are scored through the NHS Oversight Framework.

How tendering integrates

"Tendering" is four different processes under two different laws, and which one applies is decided by *what* is being bought, not by who is buying it. Treating them as one thing is the most common way a launch loses a quarter.



The Provider Selection Regime never touches your product. It came into force on 1 January 2024 for healthcare services and expressly excludes goods, medicines included. The medicine, the logistics and the consumables all sit under the Procurement Act 2023, live since 24 February 2025.

What competition actually looks like

For a single-source, patent-protected ATMP there is normally **no competitive tender for the product**. It reaches centres through a national framework listing or a direct award set against the NICE-mandated commercial agreement, run by NHS England's Medicines Procurement and Supply Chain function (the former CMU) within Medicines Value and Access. Competition arrives only when a rival product or a biosimilar does — at which point the same framework becomes the battleground and switch decisions move to regional hubs and trust D&T committees.

The Procurement Act changed the terms in ways worth knowing: frameworks can now run **eight years rather than four**, with open procedures to add suppliers mid-term; award moves from Most Economically Advantageous Tender to **Most Advantageous Tender**, which admits more than price; exclusion grounds widen to cover underperformance; and contracts over £5m carry published KPIs and annual performance notices.

What the role actually owns

You never run the tender — the ICB or the trust does. The job is to make their process cheap and fast: a complete, compliant supplier response pack held ready; correct registration on the Central Digital Platform and monitoring of Find a Tender; substantive input during preliminary market engagement, which is permitted and expected; KPI evidence assembled early for contracts above the £5m threshold; and a live tracker of every centre's contract expiry, framework end date and standstill window.

The direction of travel matters too. The Medium Term Planning Framework and the Single National Formulary both push toward fewer, more national arrangements — so a strong national framework position will be worth progressively more, and local tendering progressively less, between now and 2030.

Where the PSR bites — and where it trips

Service provision at your ten or eleven centres is a PSR decision made by the commissioner, not by you. Retaining an existing centre usually runs through **Direct Award Process C** or the **Most Suitable Provider** route; standing up new ones needs a **Competitive Process**. All three require the five key criteria to be weighted and recorded, an intent-to-award notice, and an **eight working-day standstill** before the contract can be signed.

The trap is Direct Award C's ceiling: it cannot be used where the change exceeds **£500,000 and 25% of the original contract value**, or where the contract's character fundamentally changes. Adding a high-cost cell therapy to an existing service contract can breach both — converting what everyone assumed was a paperwork exercise into a competitive process nobody scheduled.

Sequencing, which is the whole game

Procurement is not one gate at the end; it is several, and they have to land in the right order. Preliminary market engagement and planned procurement notices can be published **before** a NICE decision — that is the window in which a specification can still be shaped to reflect what the therapy actually needs. The framework listing has to be live at the funding mandate. The PSR standstill has to be inside the activation date, not after it. The homecare or logistics contract is almost always the last thing anyone starts and the first thing that slips.

And each centre runs its own trust procurement calendar with its own contract expiry dates. Eleven centres means eleven clocks.

The finance gatekeepers

Market access people over-index on commissioners and clinicians. In a system running at the edge of its allocation, the finance line is where a designated centre quietly declines to activate. Three roles matter, and they want different things.

DHSC Director General of Finance & the NHS Group CFO

SETS THE ENVELOPE · NATIONAL

The DG Finance owns the departmental settlement and issues the annual *financial directions* that bind NHS England — and, as NHS England is absorbed into the department, increasingly owns the group financial position outright. This is the level at which the medicines bill is traded against everything else: workforce, capital, waiting lists.

You will never meet this person, but you feel them. The VPAG rebate, the statutory scheme review and the affordability conversation around a high-cost one-shot therapy all resolve here. It is also why a favourable NICE recommendation can still arrive alongside a commercial ask for staged payment — the department is managing in-year cash, not lifetime value.

IMPLICATION Frame the therapy's budget impact in-year and in cash, not in QALYs. Displacement arguments — transplants avoided, ITU bed-days released — travel further at this level than efficacy.

ICB Chief Finance Officer

HOLDS THE PATHWAY · SYSTEM

The ICB CFO is a statutory board officer running the system's revenue position. In 2026/27 ICBs already hold around 70 delegated specialised services worth roughly £14bn against a needs-weighted formula, and under the Health Bill they become strategic commissioners holding over 90% of commissioning budgets — about £179bn from 2027/28. They are doing this while merging with neighbours in April 2026 and 2027 and cutting running costs by around half.

Critically: **the drug is not their problem, but the pathway is.** Referral and workup in a district general, transport, diagnostics, follow-up, and the non-drug cost of the treatment episode sit in their ledger. A CFO facing a deficit plan has every reason to slow a pathway that imports cost into their system so a tertiary centre can deliver a nationally funded therapy.

IMPLICATION Bring a pathway cost model that separates nationally funded drug cost from locally borne activity, and be honest about the second number. Identify the ICB CFO and their medicines/finance lead in each catchment early — the merger churn means that person may have changed twice since your last account plan.

Trust Director of Finance

CARRIES THE RISK · PROVIDER

At each of your ten or eleven centres, the DoF signs off whether the service can go live. Under the Health Bill each organisation becomes accountable for its own financial performance rather than system balance, which sharpens this considerably — the trust cannot lean on the system to absorb a loss.

Their specific anxieties: the trust buys and holds a very expensive product before it recovers the cost; recovery depends on a correctly completed Blueteq form and a validated commissioner claim; an outcome-based deal creates a receivable that may not land for a year; and the excluded-drugs list moves — 2026/27 pulled a tranche of homecare drugs into tariff, so "is it still excluded?" is a live annual question. Meanwhile the staffing, aseptic capacity and bed-days needed to deliver the therapy are not reimbursed by the drug line at all.

IMPLICATION The DoF conversation is about working capital and leakage, not value. Bring the Blueteq criteria pre-mapped to the local coding, a clear statement of who invoices whom, and evidence that other designated centres have recovered cleanly.

Where launches actually stall

Centre activation drift Designated on paper, not staffed or accredited in practice. Slippage here is invisible in national data and fatal to a launch curve.	**Unfunded pathway cost** Drug funded nationally; workup, apheresis and follow-up funded by nobody in particular. The gap lands on the ICB or the trust and neither volunteers.	**Blueteq mismatch** Form criteria that do not map to how clinicians actually document eligibility. Rejected claims teach a trust to be cautious about the next patient.	**Referral flow** Most patients sit in trusts that will never treat them. Without a working referral route into the designated centre, capacity goes unused.
Managed access data burden An IMF or CDF agreement needs outcomes captured at centre level. If nobody is funded to collect it, the exit review is the risk.	**Commissioner churn** ICB mergers, NHS England wind-down and the move to OPICs from 2027 mean relationships and institutional memory keep resetting.	**Procurement mis-routing** A single-source ATMP run as if it needed competition, or a Direct Award C that breaches its value ceiling — either turns weeks into a quarter.	**Homecare contract lag** The delivery and cold-chain arrangement is started last and let slowest, stranding a centre that is otherwise ready to dose.

The 2026 backdrop

NICE THRESHOLD

£25–35k

Per QALY from April 2026, up ~25% — expected to admit three to five more medicines or indications a year.

VPAG REBATE

15%

For 2026, down from a 23.5–35.6% range, following the December 2025 UK–US pricing agreement.

ICB COMMISSIONING

£179bn

Over 90% of NHS commissioning budgets under ICB control from 2027/28 as strategic commissioners.

STRUCTURAL CHANGE

2027

NHS England functions transfer to DHSC; highly specialised commissioning moves to the department, supported by seven regional OPICs.

SINGLE NATIONAL FORMULARY

July 2027

First four therapy areas live; standardised categories in 13 early-adopter ICBs from December 2026, all ICBs by July 2027.

What a credible account plan contains

- → **Activation status per centre** — accreditation, licences, aseptic and apheresis capacity, named clinical lead, realistic first-dose date.
- → **Named finance contacts** — trust DoF or deputy, ICB CFO and medicines finance lead, refreshed after each merger.
- → **Pathway cost model** — drug versus non-drug, national versus local, per treatment episode.
- → **Blueteq readiness** — form live, criteria mapped to local documentation, first claims tracked to payment.
- → **Referral catchment map** — which spokes feed which hub, and where the route does not yet exist.
- → **Managed access obligations** — who collects what, funded how, against which exit review date.
- → **Procurement position** — framework listing and end date, contract vehicle, tariff-exclusion status confirmed for the current year, and each centre's contract expiry and standstill windows.
- → **Cross-functional asks** — what Medical, External Affairs and Commercial each owe the plan, with dates.

SOURCES

A guide to specialised commissioning in 2026/27 — SHCA

Innovative Medicines Fund — NHS England

Health Bill: ICBs as strategic commissioners — GOV.UK

NICE threshold reform, VPAG and trade signals — pharmaphorum

Strategic commissioning framework — NHS England

2026/27 Standard Contract service conditions (SC2, SC20, SC27)

Quality and Outcomes Framework guidance 2026/27

Progress with England's Single National Formulary — pharmaphorum

Provider Selection Regime FAQs — NHS England

Delegation of specialised services to ICBs — NHS England

NHS commercial framework for new medicines

2026/27 financial directions to NHS England — DHSC

Medicines Procurement and Supply Chain frameworks — NHS SPS

Medium Term Planning Framework 2026/27–2028/29

Sepsis modern service framework — NHS England

NHS Oversight Framework 2026/27

Key changes in the 2026/27 NHS Standard Contract — Lexology

UK public procurement transformed: what it means for medicines — Arnold & Porter

Advanced therapy medicinal products — NHS England

2026/27 NHS Payment Scheme

ICB mergers and boundary changes, April 2026 and 2027

Medium Term Planning Framework: revenue finance and contracting

NHS Standard Contract 2026/27 — NHS England

Understanding the CVD modern service framework — Carnall Farrar

Delivering the Single National Formulary — NHS England

Provider Selection Regime: statutory guidance — NHS England

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COMPILED SEPTEMBER 2026 · POLICY POSITIONS CURRENT AT TIME OF WRITING