Who Pays for a NICE-Approved Non-Statin Lipid-Lowering Therapy?

Commissioning architecture, funding flows, contracting levers and tendering routes in England — compiled 21 September 2026

This briefing takes a single question and answers it end to end: if you are bringing a first-in-class, NICE-recommended non-statin lipid-lowering therapy to the NHS in England, who actually pays for it, through which instrument, and who signs. It is written for a Market Access or Key Account role working cross-functionally with Medical, Commercial and External Affairs — the person who has to build account plans, navigate the funding pathway and get through local and regional tendering. It covers England. Scotland, Wales and Northern Ireland run separate HTA, contracting and procurement machinery and are out of scope here.

Health warning. The NHS commissioning architecture is in flux. Integrated care boards are consolidating from 42 towards roughly 26, NHS England is being folded into the Department of Health and Social Care, the Strategic Commissioning Framework only took effect from November 2025, and the CVD Modern Service Framework published on 7 July 2026 is still waiting on its national delivery plan. Named documents, point values, payment rates and organisational boundaries in this briefing were current when it was compiled. Check each one against the live source before you put a number in front of a finance director.

Executive summary

A NICE technology appraisal creates a legal funding obligation. It does not create a budget line, a pathway position, a prescriber, or a route to the patient. For a non-statin lipid-lowering product, the gap between the obligation and the money is unusually wide, because almost all of the eligible population sits in primary care — where there is no tariff, no commissioner-to-provider contract for medicines, and no tendering process to win.

Six things follow from that, and they shape everything else in this briefing.

1. The commercial deal is national, not local. The inclisiran precedent is the template: NHS England negotiated a confidential contract price with the manufacturer, set a Drug Tariff reimbursement price, and paid the difference centrally so that local prescribing budgets were not a barrier. If your product does not secure something structurally similar, 42-going-on-26 area prescribing committees decide your access one at a time.
2. Your budget holder in primary care is the ICB prescribing budget, and it is already under pressure. Absent a national arrangement, the cost lands on ICB delegated primary care prescribing spend — the single most scrutinised line in an ICB finance report.
3. The NHS Payment Scheme is largely irrelevant to you until the product is specialist-initiated. It matters for the secondary care lipid clinic and the acute cardiology pathway — through exclusion from national prices and locally agreed cost-and-volume — not for the 90%+ of eligible patients managed in general practice.
4. QOF is statin-first by design, and this is your most underestimated barrier. CHOL003 credits a practice for prescribing a statin; non-statin agents count only where statin intolerance or an adverse reaction is documented. CHOL004 rewards reaching the LDL-C target by any means. Your commercial argument to a practice runs through CHOL004, not CHOL003.
5. The CVD Modern Service Framework is the strongest tailwind a lipid product has had in a decade. Twelve priorities, two of them explicitly lipid optimisation — one for people without established CVD, one for people

with it — with baselines, three-year targets and ten-year ambitions, an ICB-level CVKM clinical lead to hold them, and variation between best and worst performers counted as a delivery failure in its own right.

6. The Oversight Framework gives you a board-level hook. "Deprivation gap in lipid and hypertension management" is a scoring metric in the 2026/27 NHS Oversight Framework. That is an inequalities argument that moves an ICB chief executive, not just a medicines optimisation pharmacist.

The practical consequence: your account plan is not a formulary plan. It is a case-finding and treat-to-target plan, in which your product is one component of a pathway the system is already accountable for delivering.

At a glance

Instrument	What it controls	Your principal lever
NHS Payment Scheme 2026/27	How commissioners pay secondary care providers; which drugs are excluded from national prices and funded separately.	Get the product onto the excluded-drugs list (Annex A) for specialist-initiated use; agree cost-and-volume locally.
Strategic Commissioning Framework (Nov 2025)	How ICBs behave as strategic commissioners: population segmentation, risk stratification, outcomes-based commissioning.	Supply the risk-stratified cohort analysis the ICB intelligence function has not yet built. Cardiovascular is a named early focus.
NHS Standard Contract 2026/27	The contract between commissioners and providers — including the obligation to comply with NICE technology appraisals.	Use the NICE funding clause to close the gap between an approved TA and a provider that will not initiate.
Medium Term Planning Framework 2026/27–2028/29	Three-to-five year system plans, 15 headline success measures, financial balance by 2029.	Land in the plan cycle, not between cycles. CVD premature mortality reduction is an explicit national ambition.
Better Care Fund 2026/27	Pooled NHS/local authority budgets under s75, governed by Health and Wellbeing Boards.	Realistically nil for the drug. Usable only for wraparound case-finding and community delivery.
Quality and Outcomes Framework 2026/27	What general practice is paid to do — including the two cholesterol indicators.	CHOL004 (treat to LDL-C target) is your route. CHOL003 is statin-first and will work against you unless intolerance is documented.
NHS Oversight Framework 2026/27	How ICBs and providers are segmented, scrutinised and escalated. 85 metrics, seven domains.	The deprivation gap in lipid management is a scoring metric. This is your board-level conversation.
CVD Modern Service Framework (Jul 2026)	The ten-year national strategy for heart disease and stroke: 12 priorities, CVKM approach, ICB accountability.	Priorities 5 and 7 are lipid optimisation. Map your product to a named priority with a named owner.
NICE NG238 and the national lipid pathway	Where each agent sits in the treatment algorithm and who may initiate it.	Pathway position determines prescriber, setting and budget. Fight this battle before the formulary one.

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1. What "NICE approved" does and does not buy you

What it does buy

A positive NICE technology appraisal triggers the statutory funding requirement: commissioners must make funding available so the technology can be prescribed for patients meeting the appraisal criteria, normally within three months of final guidance. That obligation is written through into the NHS Standard Contract, so a provider refusing to offer a recommended technology to an eligible patient is in breach of contract, not merely out of step with guidance.

What it does not buy

- A budget line. The obligation is to fund; it does not say from whose budget, in which setting, or at what pace.
- A pathway position. NICE NG238 and the NHS England national lipid management pathway decide where your product sits and who may start it. That is a separate and usually harder fight than the TA.
- A prescriber. If the pathway places you after maximally tolerated statin plus ezetimibe, you need a general practice — or a practice pharmacist — to find the patient, check the lipid profile and act. None of that is automatic.
- A supply route. Inclisiran needed a bespoke Drug Tariff Part VIIIC entry, a nominated wholesaler and a central top-up payment before primary care could realistically use it. Do not assume a route exists.
- Speed. The funding requirement sets a floor for availability, not a ceiling on how slowly local systems implement it.

The first-in-class problem, specifically

A first-in-class non-statin faces three structural frictions that a me-too product does not. First, there is no existing formulary entry, no comparator line to slot into, and no local guideline text to amend — every area prescribing committee is writing from scratch. Second, the clinical community will read the TA against a statin-anchored standard of care that is decades old, cheap and generically supplied. Third, a genuinely novel mechanism attracts a "specialist initiation only" reflex from medicines optimisation committees, which is the fastest way to lose the primary care population you were priced on.

Anticipate all three. The counter to the first is a ready-to-adopt formulary application pack and pathway text. The counter to the second is a budget-impact narrative denominated in avoided events, not in cost per patient. The counter to the third is a shared care or primary-care-initiation proposition supported by a clear monitoring burden — ideally none.

2. Who holds the money

Budget holder	What they hold	Relevance to a non-statin lipid therapy
Integrated care board — primary care prescribing	Delegated prescribing budget covering FP10 prescribing by general practice.	Primary. This is where the eligible population is and where the cost lands absent a national arrangement.
NHS England — central commercial	Confidential national contract prices; central top-up payments; Drug Tariff reimbursement setting with DHSC.	The route that made inclisiran viable. If you can reach this table, reach it.
Integrated care board — acute contracts	API fixed and variable payments to acute trusts, including agreed high-cost drug exclusions.	Relevant for lipid clinics, FH services and post-event initiation in cardiology.
NHS England specialised commissioning	Directly commissioned specialised services, including severe and homozygous FH.	Narrow but high-value. A distinct commissioning conversation with a distinct sign-off.

Budget holder	What they hold	Relevance to a non-statin lipid therapy
ICB transformation / prevention funding	Non-recurrent programme money, including Prevention Accelerator sites.	Funds the case-finding and optimisation service around the drug — rarely the drug itself.
Local authority public health grant	NHS Health Checks, population prevention.	Upstream case-finding. No medicines budget, but a meaningful source of identified patients.
Better Care Fund (s75 pool)	Pooled NHS/LA money governed by Health and Wellbeing Boards.	Effectively closed to medicines. Treat as a wraparound-services lever only.

The signature list for a primary care lipid product is short and specific: the ICB chief pharmacist or director of medicines optimisation, the area prescribing committee or equivalent formulary body, the ICB CVKM clinical lead named under the Modern Service Framework, the ICB finance director for the prescribing budget line, and — where the pathway crosses into secondary care — the trust chief pharmacist and the relevant drugs and therapeutics committee. Regional medicines optimisation committees sit above the ICBs and can set a position that several ICBs then adopt; getting there early is disproportionately valuable.

3. The nine instruments

Eight national instruments govern how the money moves. A lipid product has a ninth: the guideline and pathway layer that decides where it sits and who may start it. Each is set out below as what it is, the mechanics that actually matter, and what it means for access.

3.1 NHS Payment Scheme 2026/27

What it is

The statutory scheme setting the rules by which commissioners pay providers for NHS-funded secondary healthcare in England, for the 2026/27 financial year. It establishes four payment mechanisms, of which the aligned payment and incentive (API) approach covers almost all commissioner-to-provider relationships, with low volume activity block payments for relationships expected to be worth under £1.5m a year.

Mechanics that matter

- API splits into a fixed element — non-elective activity, community, mental health, maternity, outpatient follow-ups and agreed high-cost exclusions — and a variable element covering elective activity at 100% of published unit prices.
- Certain high-cost drugs and devices are removed from unit prices and funded separately. The exclusion list sits in Annex A. For drugs remaining on it, commissioners and providers agree funding locally, typically on a cost-and-volume basis.
- Newly introduced funded high-cost drugs are excluded from the fixed element; funding must be locally agreed between provider and commissioner. This is the clause that matters most for a new specialist-initiated therapy.
- For specialised commissioning, baseline excluded drug values sit in the API fixed element and costs above that baseline are paid directly by NHS England.
- The 2026/27 cost uplift factor is provisional pending final pay settlements; a revised Annex A will be republished and backdated to 1 April 2026.
- The direction of travel is against exclusions, not for them. Several homecare drugs excluded in prior years — adalimumab and etanercept among them — have been moved back into prices for 2026/27.

Access implications

If your product will be specialist-initiated in lipid clinics or started in cardiology after an acute event, exclusion from national prices is the difference between a trust that can afford to start patients and one that absorbs your cost inside a fixed payment. Pursue exclusion, and expect to have to justify it against a scheme actively trying to shrink the list. If your product is primary care initiated, this instrument is close to irrelevant — say so plainly rather than letting a colleague build a tariff argument that does not apply.

3.2 Strategic Commissioning Framework

What it is

Published in November 2025, the framework sets out what NHS England expects integrated care boards to be: strategic commissioners accountable for best value from the NHS budget across whole pathways and populations, rather than transactional purchasers of activity.

Mechanics that matter

- ICBs must segment their populations and stratify health risk using person-level data, disaggregated to surface inequalities.
- Each ICB is required to establish an intelligence function combining strategic planning and population health management capability, fully operational by March 2027.
- Key dates: integrated needs assessments and population health improvement plans from January 2026; baseline assessment against the framework by March 2026; the strategic commissioning development programme from April 2026; NHS England assessing ICB performance as strategic commissioners during 2026/27.
- The framework encourages financial and risk-share models that incentivise partnership working, and names year-of-care and best practice tariffs as ways of aligning financial incentives with outcomes.
- The Model Health System benchmarking tool is being focused initially on cardiovascular disease, stroke and diabetes.
- It sits alongside consolidation of ICBs from 42 towards approximately 26.

Access implications

This is the most exploitable instrument on the list for a lipid product, for one reason: ICBs are being told to do population risk stratification on cardiovascular disease, and most of them do not yet have the analytical capacity to do it. A credible, methodologically transparent cohort analysis — how many people in this ICB are on a CVD register, how many have had a lipid profile in 12 months, how many are above target, how that distributes by deprivation decile — is a genuinely useful contribution that buys you a seat at the table. Build it once nationally, cut it by ICB, and hand it over. Do not disguise a sales tool as an analysis; medicines optimisation pharmacists recognise one immediately and the relationship does not recover.

Practical caution: during consolidation, the ICB you are planning with may not be the ICB that signs. Map to the emerging cluster footprint, not only the current one.

3.3 NHS Standard Contract 2026/27

What it is

The mandated form of contract between NHS commissioners and providers of healthcare services other than primary medical care. Published in December 2025 in full-length and shorter-form versions, with accompanying technical guidance.

Mechanics that matter

- Service conditions oblige providers to comply with NICE technology appraisals and highly specialised technologies guidance, making the statutory funding requirement contractually enforceable.
- For 2026/27 the escalation process around activity management was retained after consultation, but commissioners may now set an Activity Management Plan on the next Operational Day in defined circumstances.
- Commissioners are now required, rather than merely expected, to comply with specified paragraphs of the technical guidance.
- Commissioners may set local variations to certain National Quality Requirements where a different target has been agreed with NHS England — a formal shift towards locally set standards.
- The contract does not govern general practice, which is contracted through the GMS/PMS/APMS route and incentivised through QOF and enhanced services.

Access implications

The NICE compliance clause is the cleanest lever you have when a trust will not initiate a recommended therapy. Use it sparingly and never as a threat delivered by a commercial colleague — it is an External Affairs or Medical conversation with a chief pharmacist or medical director, framed as a shared problem. Its bluntness is also its limit: it compels availability, not enthusiasm, and a reluctantly compliant service will refer three patients a year.

The more important point for a primary care product is what the contract does not reach. There is no Standard Contract lever in general practice. That asymmetry is the single most common planning error in lipid launches.

3.4 Medium Term Planning Framework 2026/27 to 2028/29

What it is

NHS England's replacement for annual operational planning guidance, published in autumn 2025, setting three-to-five year expectations for systems and providers against 15 headline success measures.

Mechanics that matter

- Systems submitted initial plans before Christmas 2025 with full submissions by March 2026 — meaning 2026/27 commitments were fixed before this briefing was written.
- The financial regime assumes roughly 3% real-terms revenue growth and 3.2% capital growth, mandatory 2% annual productivity improvement, and every organisation in financial balance or surplus by 2029 without deficit support.
- A national ambition to reduce premature cardiovascular mortality by 25% by 2035 sits in the framework.
- Neighbourhood health is a central delivery vehicle: contracted integrated neighbourhood teams, mapping of care utilisation, and a shift of activity out of hospital.
- Commentary from the NHS Confederation and others notes that prevention content is comparatively sparse relative to elective, urgent care and workforce commitments.

Access implications

Two things follow. The first is timing: if your product is not reflected in a system plan, you are waiting for the next planning round, and your window for the 2027/28 refresh opens in autumn 2026 — now. The second is framing: in a planning environment dominated by waiting times, financial balance and productivity, a prevention proposition wins on avoided admissions and avoided bed days, not on clinical elegance. The North East and Yorkshire modelling published alongside the Modern Service Framework — thousands of prevented events, tens of thousands of bed days, and a nine-figure saving over three years — is the shape of argument that travels in this room.

3.5 Better Care Fund 2026/27

What it is

A mandatory pooled budget between ICBs and local authorities, created under section 75 of the NHS Act 2006, governed locally through Health and Wellbeing Boards and assured jointly by DHSC, MHCLG and NHS England.

Mechanics that matter

- Three national conditions for 2026/27: plans must align with neighbourhood health objectives and demonstrate productivity and metric impact; required funds must be pooled under s75 with the mandated uplift to the NHS minimum contribution to adult social care maintained; and joint governance with engagement in the assurance process.
- A mandatory 4.4% uplift applies to the NHS minimum contribution to adult social care.
- Metrics: emergency admissions for people aged 65 and over, discharge delays, and admissions to residential care.
- Planning assurance returns were due 19 May 2026, reviewed by joint NHS and local government regional teams.
- Priority investment areas are intermediate care, disabled facilities grants, unpaid carer support and VCSE-delivered prevention.

Access implications

Be honest with colleagues about this one. The Better Care Fund will not pay for your medicine, and a market access plan that proposes it as a funding route will damage your credibility with an ICB finance team. Its legitimate uses are narrow: community-delivered case-finding in populations the BCF already serves, VCSE outreach into underserved groups, and integration with neighbourhood teams where lipid optimisation can be bolted onto an existing frailty or long-term conditions visit. Frame any BCF conversation around the 65-plus emergency admissions metric, because that is what the Health and Wellbeing Board is actually judged on.

3.6 Quality and Outcomes Framework 2026/27

What it is

The pay-for-performance element of the general practice contract in England. For a primary-care-delivered lipid therapy it is the most directly behaviour-shaping instrument on this list, because it determines what a practice is paid to do with the patients you need it to find.

Mechanics that matter

- **CHOL003 — lipid-lowering therapy.** Covers patients on the CHD, PAD, stroke/TIA and CKD stage 3–5 registers, excluding those aged 17 and over with diabetes. The indicator is satisfied by a statin or a documented alternative. Critically, bempedoic acid, ezetimibe, inclisiran and the PCSK9 inhibitors count only where a statin adverse reaction or intolerance is documented. Point value is reduced from 38 to 20 for 2026/27; thresholds remain 70–95%.
- **CHOL004 — cholesterol treatment target.** Covers the CHD, PAD and stroke/TIA registers. LDL-C of 2.0 mmol/L or below is the primary measure, with non-HDL-C of 2.6 mmol/L or below used only where no LDL-C result exists. Thresholds 20–50%. This is the treat-to-target indicator and it is agnostic as to how the target is reached.
- Wider 2026/27 changes: two new blood pressure indicators, CD001 and CD002, replace the previous separate CHD and stroke/TIA indicators; a new four-pillar heart failure indicator, HF009; increased points on the diabetes statin indicators DM034 and DM035; AF006 threshold raised to 95%; new obesity indicators. Much of this is redistribution of existing points rather than new money.
- The 2026/27 contract carries a £485m uplift — 3.6% cash, around 1.4% real terms — with roughly £25m attached to 18 new QOF points.

- NICE maintains the underlying indicator menu, including IND278 on the secondary prevention cholesterol treatment target, updated February 2026.

Access implications

This is the sharpest point in the briefing, so state it plainly to your commercial colleagues. QOF pays a practice to prescribe a statin. It does not pay a practice to prescribe your product — unless the patient is statin-intolerant and that intolerance is recorded, or unless your product is what gets the patient to the CHOL004 target.

Two consequences. First, your primary care proposition is a CHOL004 proposition: "here is your cohort above LDL-C 2.0 on maximally tolerated therapy, here is what closing it does to your achievement." Second, documented statin intolerance is a data quality issue as much as a clinical one — practices under-code it, and a coding audit is a legitimate, non-promotional service that materially expands your CHOL003-eligible population. That work sits with Medical and with practice pharmacists, not with a sales team.

The reduction of CHOL003 from 38 points to 20 also cuts both ways: less practice attention on lipid-lowering initiation overall, but relatively more weight on the target indicator. Track the published QOF guidance for the final 2026/27 point values before quoting them.

3.7 NHS Oversight Framework 2026/27

What it is

The regime by which NHS England segments, scrutinises and intervenes in ICBs and providers. It combines delivery monitoring, capability assessment and a graduated oversight response.

Mechanics that matter

- 85 metrics across seven domains — population health, resource allocation and access, experience, effectiveness, patient safety, finance and productivity, and people. Metrics are either scoring or contextual.
- Organisations are placed in segments 1 to 4. A financial deficit blocks segment 1 or 2 until resolved. Higher segments with lower assessed capability attract the most intensive oversight.
- ICBs and providers have tailored domain structures — ICBs assessed on allocating resources, providers on access.
- **"Deprivation gap in lipid and hypertension management" is a scoring metric.** Not contextual — scoring. Lipid management performance therefore feeds directly into how an ICB is segmented and how much scrutiny its board receives.

Access implications

This is your board-level access argument and it is unusually well suited to a lipid product. The metric is not "how many people are on treatment" but the gap between the most and least deprived — which means an intervention that disproportionately reaches under-treated, under-coded, high-deprivation cohorts scores better than one that adds volume to already well-managed practices.

Design your case-finding proposition around the deprivation gap explicitly. It changes who you target within an ICB, it aligns with the Modern Service Framework's treatment of variation as a delivery failure, and it gives an ICB chief executive a reason to take a meeting that a formulary conversation never will.

3.8 Cardiovascular Disease Modern Service Framework

What it is

Published on 7 July 2026 by the Department of Health and Social Care with NHS England, the CVD Modern Service Framework is a ten-year strategy and delivery model to cut premature deaths from heart disease and stroke in England by a quarter within a decade. Around 33,000 people under 75 die prematurely from cardiovascular causes each year in England, second only to cancer, and most of those deaths are considered preventable.

Mechanics that matter

- It adopts a cardiovascular-kidney-metabolic (CVKM) approach, managing blood pressure, cholesterol, blood glucose, weight, kidney disease, atrial fibrillation and smoking together rather than as separate conditions.
- Twelve priorities sit under four themes: finding the missing millions; driving treatment to target; timely and equitable acute care; and living with cardiovascular disease.
- Two of the twelve are explicitly lipid priorities — priority 5, lipid optimisation in people without established CVD, and priority 7, blood pressure and cholesterol optimisation in people with CVD. Each priority carries a baseline, a three-year target and a ten-year ambition set out in the framework tables.
- Each ICB names a CVKM clinical lead. ICBs and local government hold outcome responsibility, with a national board and regional teams providing oversight.
- Variation is itself a measure: the gap between best and worst performers is tracked, and failing to close it counts as delivery failure regardless of overall improvement.
- The framework aligns priorities with existing incentive schemes — QOF, the Community Pharmacy Contractual Framework and acute best practice tariffs — rather than creating new payment mechanisms.
- Prevention Accelerators went live in June 2026 in five areas: Greater London, Greater Manchester, Liverpool City Region, South Yorkshire and the West Midlands.
- Projected impact: 1,600–2,400 premature deaths prevented annually by year three, rising to 3,850–4,900 by year ten. A national delivery plan and further implementation detail were expected later in 2026.
- The supporting technical annex anchors the lipid case on the established relationship that each 1 mmol/L reduction in LDL-C is associated with roughly a 22% reduction in major vascular events after the first year.

Access implications

This framework does more for a lipid product than any other document on this list, and it does it by creating named, owned, measured accountability where previously there was aspiration. Your job is to attach your product to a specific numbered priority with a specific named owner, and to arrive with the delivery gap already quantified for that ICB.

Two cautions. First, the framework establishes no new payment mechanism — it aligns to existing ones, which means the money questions in sections 3.1 to 3.6 still have to be answered. Second, as external commentary has consistently noted, the risk here is delivery rather than strategy: converting condition registers into a unified CVKM population view, building neighbourhood case-finding that reaches under-served groups, and tracking variation at practice level are all real operational problems that most systems have not solved. Every one of those is a place where a well-resourced partner can be genuinely useful, and each is more defensible than a discussion about your product's label.

The five Prevention Accelerator sites are the obvious priority accounts. They have funding, mandate, national visibility and a reason to move quickly.

3.9 The lipid guideline and pathway layer

What it is

NICE guideline NG238, Cardiovascular disease: risk assessment and reduction, including lipid modification, published 14 December 2023, and the NHS England summary of national guidance for lipid management — the treatment algorithm maintained with the Accelerated Access Collaborative and endorsed for local adoption. Together they decide where a product sits and who may start it.

Mechanics that matter

- Primary prevention: atorvastatin 20mg where lifestyle measures are insufficient, with QRISK3 for risk assessment. Secondary prevention: atorvastatin 80mg initiated immediately, or 20mg where eGFR is below 60.
- Treatment targets: non-HDL-C below 2.5 mmol/L; in familial hypercholesterolaemia a reduction of 50% or more from baseline. Therapy is intensified where non-HDL-C reduction is under 40% at three months.
- Ezetimibe is added in primary care where a statin alone does not achieve a 40% reduction. The bempedoic acid and ezetimibe combination is used in primary care where ezetimibe alone is insufficient and a statin is contraindicated or not tolerated.
- Inclisiran is prescribed in primary care where LDL-C remains at or above 2.6 mmol/L despite maximally tolerated lipid-lowering therapy, in secondary prevention.
- PCSK9 inhibitors — alirocumab and evolocumab — are specialist-initiated with defined LDL-C entry thresholds, and may then be continued in primary care.
- Regional and ICB lipid pathways are adapted from the national algorithm, which is why the national text matters: it is the parent document every local pathway is cut from.

Access implications

Pathway position is the single most consequential variable in your commercial model, because it simultaneously determines prescriber, setting, budget and eligible population size. A product positioned after maximally tolerated statin plus ezetimibe reaches a large primary care population and depends on general practice behaviour. A product positioned as specialist-initiated reaches a small, well-identified population through a contracted provider with a high-cost drug conversation. These are different businesses.

Get the national pathway updated before you invest in local formulary work. Amending the AAC algorithm and the NICE-hosted summary propagates into dozens of regional and ICB pathways automatically; winning ICBs one at a time while the national algorithm still omits you is the slowest possible route.

Note also that clinical opinion on LDL-C targets is moving — HEART UK and others have been comparing international guideline positions, and the 2026 ACC/AHA dyslipidaemia guideline has widened treatment eligibility. That is useful external context for a Medical Affairs discussion but it is not NHS policy, and presenting it as though it were will cost you credibility with a medicines optimisation committee.

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4. Funding routes ranked by realism

Route	Mechanism	Realism
National commercial agreement with Drug Tariff reimbursement	Confidential contract price agreed with NHS England; Drug Tariff Part VIIIC reimbursement price set; central payment covers the gap so local budgets are not a barrier. Practices or pharmacies purchase at the lower price and are reimbursed at the tariff price.	Highest value, hardest to get. The inclisiran precedent proves it is possible. Requires a population-scale proposition and a price the centre will accept.
ICB formulary inclusion, primary care prescribing budget	Area prescribing committee or regional medicines optimisation committee approval; cost falls on delegated ICB prescribing spend.	The default if there is no national deal. Slow, variable, and fought 26 times. Budget pressure is acute.
Exclusion from national prices, secondary care	Product added to the excluded drugs list in NHS Payment Scheme Annex A; funding agreed locally with the commissioner, typically cost and volume; Blueteq or equivalent prior approval often applied.	Realistic for specialist-initiated use. Note the scheme is actively shrinking the exclusion list.

Route	Mechanism	Realism
Specialised commissioning	Directly commissioned services — severe and homozygous familial hypercholesterolaemia.	Narrow population, cleaner funding, distinct sign-off. Worth pursuing in parallel, not instead.
Prevention Accelerator and ICB transformation funding	Non-recurrent programme money attached to the CVD Modern Service Framework and neighbourhood health.	Funds the case-finding and optimisation service, not the medicine. Use it to build the demand, not to pay for the product.
Local authority public health grant	NHS Health Checks and population case-finding.	No medicines budget. Value is in identified patients entering the pathway.
Better Care Fund	Section 75 pooled budget governed by the Health and Wellbeing Board.	Close to nil for the medicine. Wraparound community delivery only.

Note on national pricing policy. The voluntary scheme for branded medicines pricing, access and growth sets the 2026 payment rate for newer medicines at 14.5%, down from 22.9% in 2025, with a further 1% investment contribution taking the effective rate to 15.5%. The UK–US agreement caps the newer medicines rate at 15% for three years, and a redesigned scheme is expected from 2029. Older branded medicines continue to pay between 10% and 35% depending on existing NHS discounts. This does not change who signs your funding decision, but it changes the arithmetic behind the price you can offer — and it is the context in which NHS England negotiates a national agreement.

5. Tendering and procurement

Which regime applies

This is the distinction most commonly got wrong. The Procurement Act 2023 governs the supply of goods, including medicines. The Provider Selection Regime, in force since January 2024, governs the commissioning of healthcare services and explicitly does not apply to the supply of products. So if you are selling a medicine, you are in the Procurement Act. If you are proposing a service — a case-finding programme, a lipid optimisation clinic, a community delivery model — that service is commissioned under the Provider Selection Regime, on different rules, with different notices and different challenge routes.

A launch that includes both a product and a wraparound service is therefore running two procurement conversations at once, often with different people. Know which one you are in at any given moment.

National and regional medicines procurement

- The Commercial Medicines Unit is now Medicines Procurement and Supply Chain (MPSC). Its frameworks are the principal route for secondary care medicines purchasing in England.
- Eligible purchasing points include NHS secondary care and mental health trusts, hospices, prison services, ambulance services and HIV/PrEP prescribing centres. Independent sector providers are out of scope irrespective of NHS patient volume, as are general primary care providers and community pharmacies apart from limited exceptions.
- Access conditions: medicines purchased must be for NHS patients only, prices must remain confidential, monthly data must be supplied to MPSC, and purchasing must be from MPSC frameworks except where clinically justified.

- Regional procurement organisations — NHS London Procurement Partnership, NHS Commercial Solutions and their regional equivalents — run pharmacy and pharmaceutical services frameworks alongside the national route. Regional tendering is where a national framework position is converted into actual volume.

What the Procurement Act changed

- Two main routes: the open procedure for routine purchasing, and the competitive flexible procedure, which permits negotiation and is better suited to complex or novel products.
- Framework agreements can now run up to eight years, and new suppliers can be appointed within the lifetime of a framework — important in a market where entrants and generics arrive mid-term.
- Pre-tender transparency is strengthened: planned procurement notices and preliminary market engagement notices replace prior information notices. Watching these is how you see a tender coming.
- Contracts above £5m carry mandatory KPIs with published annual performance notices. Exclusion grounds are broader, covering poor past performance, labour standards and national security.
- The window to challenge is tight — 30 calendar days. Decide in advance who in your organisation makes that call and how fast they can be reached.

The honest position for a primary care product

There is no tender to win for a medicine prescribed on FP10 in general practice. Supply runs through the Drug Tariff, wholesalers and community pharmacy, not through a competitive award. Colleagues who have come from a secondary care or device background will look for a tender process and will not find one; the equivalent gate is formulary inclusion and pathway position. Say this early and repeatedly, because an account plan built around a procurement event that does not exist wastes a launch year.

6. Cross-functional operating model

Function	Owns	Cannot own
Market Access / Key Account	The funding route, the budget holder map, formulary and pathway submissions, the ICB and regional account plan, procurement and framework engagement.	Clinical discussion beyond the label; direct service design with a provider without Medical involved.
Medical	Evidence generation and dissemination, clinical engagement with lipid leads and CVKM clinical leads, guideline and pathway submissions, coding and data quality support, health economic and budget impact models.	Anything that reads as promotional; commercial terms.
Commercial	Forecasting, pricing and contracting execution, territory deployment, performance tracking.	Ownership of the funding conversation; any leading role in a formulary or pathway submission.
External Affairs	National policy engagement, the NHS England and DHSC relationship, Modern Service Framework and delivery plan influence, charity and professional society partnerships, Prevention Accelerator relationships.	Local account execution; anything that cuts across a live commercial negotiation.

The interface that most often fails on a product like this is Market Access and Medical at the pathway stage. Getting a product into the national lipid algorithm is a clinical and evidential argument made to clinical people, but its consequences are entirely commercial. Run it as one workstream with one plan and one owner, or the

pathway submission will be built without reference to the budget impact case and the budget impact case will assume a pathway position that was never secured.

The second common failure is External Affairs and field access operating on different clocks. National policy influence on the Modern Service Framework delivery plan and local ICB engagement need to be sequenced deliberately: a national position secured after the ICBs have already written their plans arrives a year late.

7. Account plan architecture and planning calendar

Account plan architecture

For a primary care lipid product the account is the ICB, with the practice or primary care network as the unit of delivery and the regional medicines optimisation committee as a gate above. Build every plan on the same five layers.

7. Cohort. How many people in this ICB sit on the CHD, PAD, stroke/TIA and CKD registers; how many have had a lipid profile in the last 12 months; how many are above LDL-C 2.0 mmol/L on maximally tolerated therapy; how that distributes by deprivation decile and by practice. This is the foundation of everything else and it is also what the ICB intelligence function needs and does not yet have.
8. Accountability. Which Modern Service Framework priority this maps to — priority 5 or priority 7 — who the named CVKM clinical lead is, what the ICB's Oversight Framework position is, and where its deprivation gap in lipid management sits relative to peers.
9. Money. Which route applies here: national arrangement, ICB prescribing budget, or high-cost drug exclusion in the acute contract. Who signs. What the budget impact is at realistic uptake, stated over three years, with avoided events costed.
10. Pathway. Where the product sits in the ICB's adopted lipid pathway today, what needs to change, who amends it, and when that committee next meets.
11. Delivery. What actually has to happen for a patient to be treated: search, recall, review, initiate, monitor. Who does each step, whose time it takes, and what you can legitimately do to reduce that burden.

Planning calendar

Window	What is happening	What you should be doing
Autumn	System planning round for the following financial year; medium-term plan refresh.	Land your cohort analysis and budget impact case before plans are written. This is the highest-leverage month of the year.
December to March	Plan submission and sign-off; NHS Standard Contract and Payment Scheme published for the coming year; GP contract and QOF changes announced.	Confirm whether exclusions, indicator changes or contract wording have moved. Update the case immediately.
April	New financial year; new QOF year; new prescribing budgets; BCF planning underway.	Formulary and pathway submissions land into fresh budgets rather than exhausted ones.
May	BCF assurance returns; Q4 and year-end performance visible.	Use CVDPREVENT and QOF achievement data to show the gap in hard numbers.
Through the year	Area prescribing and regional medicines optimisation committees meet on fixed cycles; Oversight Framework segmentation reviewed.	Track committee dates per ICB. Missing a cycle costs a quarter; missing two costs a launch year.

8. Objections and the answer shape

"We already have statins, and they are pennies."

Agree with the premise and move the question. High-intensity statins are and remain first-line; nothing you are proposing changes that. The question is what happens to the sizeable cohort already on maximally tolerated therapy and still above target — a cohort the ICB can count from its own data and is now accountable for under Modern Service Framework priority 7. Bring the number. The argument fails when it sounds like displacement and works when it sounds like completion.

"Our prescribing budget cannot take it."

This is usually true and should be treated as a genuine constraint, not an objection to overcome. Ask what the arrangement is: if a national agreement with a central top-up exists, the local budget exposure is different from what the finance team assumes, and that fact often has not reached them. If there is no such arrangement, be straight about it and shift to phasing, cohort prioritisation by risk and deprivation, and a three-year budget impact rather than a first-year one.

"This should be specialist-initiated."

The strongest counter is the monitoring burden, not the clinical argument. Set out precisely what initiation requires in primary care, what monitoring is needed, and what happens if it is not done. If the honest answer is that the burden is low, the specialist-initiation reflex is hard to sustain. If the honest answer is that it is substantial, say so and propose shared care with a written protocol rather than losing the argument twice.

"Show me this does not just widen inequalities."

This is the best objection you will receive and it deserves a real answer. Under both the Oversight Framework scoring metric and the Modern Service Framework treatment of variation, an intervention that improves the average while widening the gap is a failure. Come with a case-finding design that targets under-treated, under-coded, high-deprivation cohorts first, and with a commitment to report the gap, not just the total.

"We are mid-merger — come back when we know who we are."

Legitimate, and pushing against it does not work. Use the period to do the analytical work, build the relationship with the CVKM clinical lead who will carry over, and map to the emerging cluster footprint. Systems in transition still have to submit plans and still get segmented.

"There is no evidence this works in our population."

A Medical conversation, not a commercial one. Hand it over properly rather than half-answering it. What Market Access can add is the implementation evidence — what happened in the Prevention Accelerator sites, what the comparable ICB did, what the delivery model cost in staff time.

Not advice — a map.

Compiled 21 September 2026. Every material claim in this briefing is traceable to a primary source listed below. NHS commissioning architecture changes frequently; verify against the live source before relying on any figure.

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