Leqembi IQLIK PDUFA Delay & Alzheimer's Care Economics

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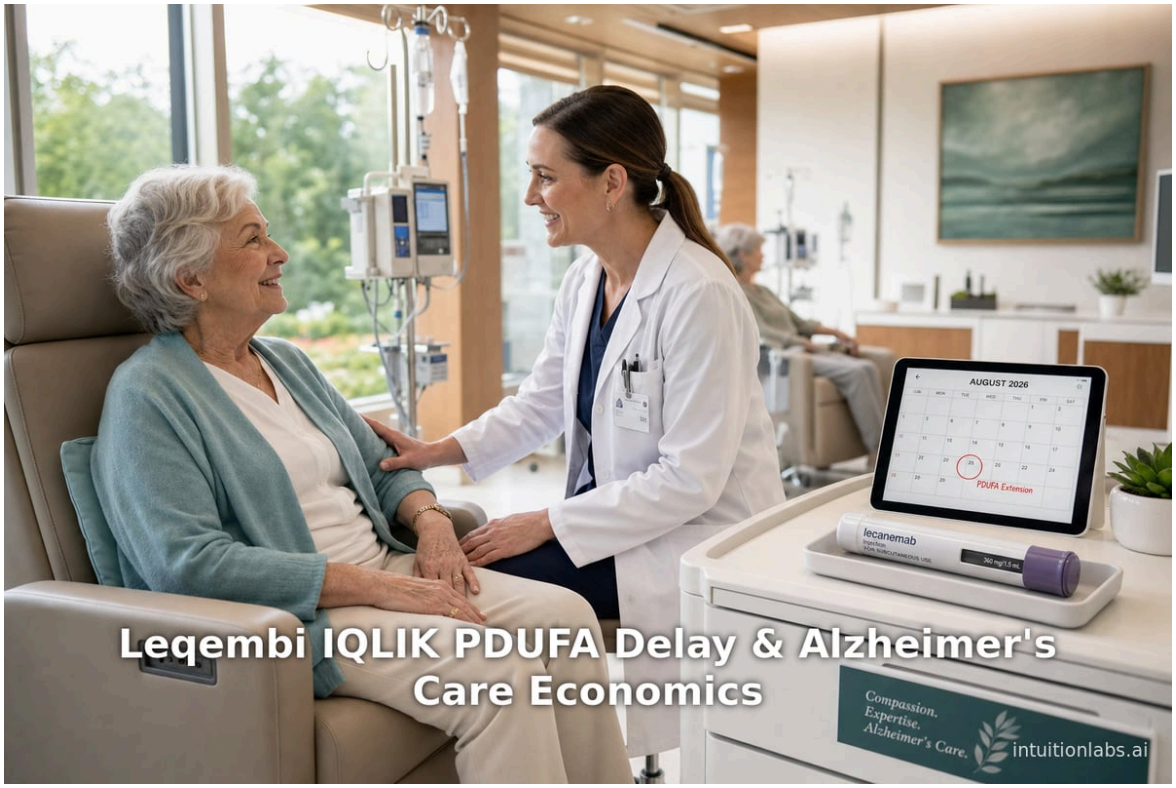

Executive Summary

Leqembi (lecanemab-irmb) is a recently approved anti-amyloid Alzheimer's therapy originally delivered by bi-monthly IV infusion. Eisai and Biogen's new subcutaneous autoinjector formulation, **LEQEMBI IQLIK**, received FDA approval in August 2025 for maintenance dosing ([1] www.eisai.com). Its full use, however, depends on the outcome of a supplemental Biologics License Application (sBLA) for using the injection **as a starting dose** in early Alzheimer's disease. On May 8, 2026, the FDA announced it had **extended the PDUFA review deadline by three months to August 24, 2026**, after treating the sBLA as a *major amendment* ([2] investors.biogen.com) ([3] www.prnewswire.com). Importantly, the agency stated it has ***no approvability concerns*** to date for the injection form ([4] investors.biogen.com) ([3] www.prnewswire.com).

This delay under FDA's Priority Review highlights both regulatory and commercial considerations. From a patient and provider perspective, the IQLIK autoinjector promises to **expedite dosing** (15 seconds versus ~1 hour for infusion) and **reduce systemic reactions** (≈1% vs 26%) ([5] www.globenewswire.com). Eisai/Biogen envision that at-home injection will *"provide greater flexibility and choice"* in anti-amyloid delivery ([6] investors.biogen.com) ([1] www.eisai.com), potentially freeing up infusion chair capacity and improving access. For example, modeling studies indicate U.S. infusion capacity for Alzheimer's treatments is far below projected demand (a forecast shortfall of >13 million infusions by 2033 ([7] www.citedrive.com)). Real-world analyses likewise show many high-prevalence counties have few or no Leqembi infusion sites ([8] bpprod.resourcestack.com) ([9] bpprod.resourcestack.com), so home injection could dramatically reduce travel burdens and clinic bottlenecks.

At the same time, the economics are challenging. Leqembi carries a very high price (~$26,500/year for IV) and even the IQLIK pen costs ~$19,500/year without insurance ([10] time.com). A recent cost-effectiveness analysis concludes Leqembi is ***not*** cost-effective at current prices (requiring a price around ~$5,100/yr to break even) ([11] journals.lww.com). Payers and governments have struggled with coverage: for example, Spain initially refused public reimbursement citing the €24,000/year cost ([12] cadenaser.com), while Medicare covers lecanemab only with strict registry requirements (imposing a 20% coinsurance up to ~$2,000/yr on seniors) ([13] www.cms.gov). These considerations – pricing pressures, payer policies, infusion capacity and patient access – provide the broader context for the IQLIK PDUFA extension. The following report examines each dimension in depth: the history and current status of anti-amyloid therapies, the clinical data and regulatory timeline for Leqembi IQLIK, the economics of launching a costly dementia drug, and the potential impacts (and opportunities) for infusion centers. We draw on trial results, company filings, policy reports and expert analyses to provide a thorough, evidence-based treatment of the topic.

Introduction and Background

Alzheimer's disease (AD) affects millions of aging Americans and is a leading cause of dementia and disability ([14] www.alz.org) ([15] www.axios.com). Current estimates exceed **7 million Americans** living with Alzheimer's in 2024 ([14] www.alz.org) ([15] www.axios.com), and numbers are projected to nearly double by 2050. The human and economic toll is immense: the Alzheimer's Association predicts AD-related health and long-term care costs of about **$410 billion in 2026**, ballooning toward $1 trillion by mid-century ([16] www.alz.org). Until recently, treatments for AD have focused on managing symptoms; no approved drug decisively alters disease progression.

A major advance came with the amyloid hypothesis: that Aβ protein aggregates drive neurodegeneration. Clearing amyloid plaques via monoclonal antibodies has been a central strategy. **Leqembi** (generic lecanemab-irmb) is one of the first such disease-modifying treatments shown to slow cognitive decline in early-stage AD. Lecanemab is a humanized monoclonal antibody targeting soluble protofibrils of beta-amyloid, thereby reducing plaque burden ([17] www.globenewswire.com). In a pivotal Phase 3 trial (Clarity AD), lecanemab infusion significantly slowed cognitive decline (primary endpoint CDR-SB difference -0.45 over 18 months, p=0.00005) relative to placebo ([18] www.globenewswire.com). The U.S. FDA granted full approval of Leqembi (IV infusion) in January 2023 for patients with mild cognitive impairment

or mild dementia due to AD, after amyloid confirmation via PET or CSF biomarkers. Subsequently, dozens of countries approved it, and Medicare instituted a coverage-with-evidence framework requiring registry participation ([19] www.cms.gov).

Infusion Requirements and Safety. Importantly, Leqembi's IV formulation carries notable logistical and safety considerations. Standard initiation is 10 mg/kg via IV infusion every two weeks for 18 months, followed by a maintenance regimen (originally monthly IV) ([20] www.globenewswire.com). Each infusion requires about **1 hour in an outpatient infusion center** plus monitoring. Biweekly to monthly infusions, plus serial MRI scans to watch for amyloid-related imaging abnormalities (ARIA), create a significant burden for patients/caregivers and for clinic schedules.ARIA is a class effect: lecanemab induced ARIA (both edema and microhemorrhages) in ~21% of treated patients (13% with edema) ([21] investors.biogen.com) ([22] www.globenewswire.com). There were also infusion-related reactions: nearly 26% of lecanemab IV infusions had some IRR (mainly mild flu-like symptoms) ([23] www.globenewswire.com). APOE ε4 patients had higher ARIA risk, mandating genotyping prior to treatment ([24] investors.biogen.com) ([25] www.globenewswire.com).

These factors limit widespread adoption. From a patient perspective, frequent two-visit trips to a clinic (for infusion and for MRI) are difficult, especially for frail seniors. Patient advocacy groups have noted that **travel distance is a key barrier**. For example, Voices of Alzheimer's president Jim Taylor observed that patients often face very long drives to the few available infusion centers, making travel time "a factor in the decision to take the drug" ([9] bpprod.resourcestack.com). A recent mapping analysis confirmed serious gaps: many high-prevalence counties have few or no AD infusion sites offering Leqembi ([8] bpprod.resourcestack.com). In several rural or majority-minority regions, patients drive dozens of miles per treatment visit, with no transportation reimbursement under Medicare.

From the healthcare system side, infusion suite capacity is strained and expensive. A recent modeling study predicted that U.S. capacity for AD infusions is far short of future need. Even with optimistic assumptions, annual infusion capacity (across all provider types) may rise from ~370,000 in 2024 to ~5.2 million by 2033; yet projected demand could exceed capacity by over 13 million infusions in 2033 ([7] www.citedrive.com). A complementary model similarly found that, even if all available infusion capacity were dedicated to AD therapies, only short-term regimens could be fully met; **chronic infusions** would outstrip supply ([26] www.citedrive.com). This underscores that without new approaches, many eligible patients would face delays or be unable to access therapy.

Market economics are another constraint. Leqembi is priced very high. Its **list price** in the U.S. is about $26,500 per year of treatment (the price was set to match Aduhelm's initial price) ([11] journals.lww.com). After discounts, net costs are somewhat lower (one report notes ~$13,316 net per year for maintenance infusion ([10] time.com)), but payers still face a steep bill if uptake expands. U.S. Medicare covered Leqembi under Part B upon full approval, with a registry requirement: eligible patients pay 20% coinsurance after deductible, effectively capping out-of-pocket at roughly $2,000 annually ([13] www.cms.gov). Commercial insurers vary; many require specialist administration and prior authorization. Internationally, cost-effectiveness assessments have flagged the high price: e.g. the German HTA body (G-BA) found "no proven additional benefit" at current price (www.kbv.de), and Spain's health ministry initially declined coverage partly on budgetary grounds, citing a cost ~€24,000/year ([12] cadenaser.com).

Emergence of IQLIK (Subcutaneous Lecanemab). Against this backdrop, Eisai developed a subcutaneous autoinjector form of lecanemab (branded IQLIK, pronounced "I-Click"). The strategy is to decouple the maintenance phase from infusion logistics. In August 2025, the FDA approved subcutaneous IQLIK for maintenance dosing: after the standard 18-month IV initiation, patients could switch to weekly self-injection of 360 mg instead of monthly infusion ([20] www.globenewswire.com) ([27] www.eisai.com). The IQLIK pen (containing 360 mg lecanemab in 1.8 mL) delivers the dose in **~15 seconds** (using an auto-injector) ([27] www.eisai.com). Clinical trial data showed that transitioning to weekly injection maintained the same slowing of cognitive decline and amyloid reduction as continuing infusion. Notably, systemic infusion reactions nearly disappeared (<1% with IQLIK vs ~26% with IV) ([28] www.globenewswire.com), and no serious injection-site events occurred. Mild local redness or itching occurred in ~11%, but did not interrupt therapy ([23] www.globenewswire.com).

IQLIK's approval was hailed as a major innovation. Eisai's CMO said it "is really going to change patient treatment," highlighting that it provides *"greater flexibility"* ([29] time.com) ([1] www.eisai.com). TIME magazine named it a "Best Invention of 2025" for enabling at-home continuation of therapy ([1] www.eisai.com) ([27] www.eisai.com). Importantly, the autoinjector **frees up infusion centers**: Eisai notes the SC option *"has the potential to reduce healthcare resources associated with IV maintenance dosing (such as infusion preparation and nurse monitoring) while increasing infusion capacity for new eligible patients"* ([30] www.eisai.com) ([23] www.globenewswire.com). In practice, this means infusion suites could potentially treat more *new* patients starting the 18-month induction, since existing patients could self-inject maintenance at home.

Despite these advances, a major gap remains: **the starting dose regimen**. Under current FDA labeling, IQLIK injections are only approved as the follow-on maintenance dose after IV induction. The new submission (sBLA) under review seeks approval to **use IQLIK injections from treatment initiation ("starting dose")** in early AD. If granted, it would allow patients to begin therapy entirely via weekly injections, potentially eliminating the need for any infusion visits. Eisai has amassed data on IQLIK in multiple dosing regimens and believes it supports this use ([31] www.prnewswire.com). The FDA's decision on this sBLA has been under Priority Review, and the recent three-month extension shifts the target date to August 24, 2026 ([2] investors.biogen.com) ([3] www.prnewswire.com).

In the sections that follow, we delve into each facet of this development: the clinical rationale for subcutaneous dosing, the regulatory timeline and significance of the PDUFA extension, the economics of rolling out another expensive anti-amyloid therapy, and the anticipated impacts on infusion centers and patient care. Numerous data sources and expert analyses are synthesized to provide a comprehensive picture of what the IQLIK injection means for the Alzheimer's treatment landscape.

Leqembi (Lecanemab) and the Anti-Amyloid Landscape

Therapeutic Context and Efficacy of Lecanemab

Alzheimer's disease is defined pathologically by amyloid-β plaques and neurofibrillary tau tangles. The "amyloid cascade" hypothesis posits that removing Aβ can slow neural damage. Lecanemab is engineered to bind soluble Aβ protofibrils, facilitating their clearance. In the **Clarity AD** Phase 3 trial (Biogen/Eisai), lecanemab infusions (10 mg/kg biweekly) slowed cognitive decline by a small but statistically significant margin. Patients on lecanemab saw a **0.45 point smaller increase** (worsening) in CDR-Sum of Boxes at 18 months vs placebo (P=0.00005) ([18] www.globenewswire.com). Secondary endpoints for memory and function also favored treatment. Long-term extension data (48 months) suggest a cumulative benefit (Slowed decline roughly -1.7 CDR-SB points vs natural history ([32] www.globenewswire.com)). These results led to FDA approval in Jan 2023 for mild cognitive impairment (MCI) or mild dementia due to AD ([33] www.marketscreener.com) ([20] www.globenewswire.com).

Lecanemab's efficacy, while modest on cognitive scales, was significant enough that AD experts and families have viewed it as the most promising therapy to date. Even a partial slowing of decline can potentially delay institutionalization. Importantly, lecanemab showed similar effect across APOE genotypes, although risk of ARIA was higher in ApoE ε4 homozygotes ([24] investors.biogen.com) ([34] investors.biogen.com). By mid-2023, Medicare expanded its coverage assuming participation in a national registry ([19] www.cms.gov), and many neurology centers began offering infusions to eligible patients.

Other anti-amyloid drugs are in development or recently approved (e.g., Donanemab by Lilly was FDA-approved in Jan 2024 under accelerated approval, with conditional confirmatory trials). Aduhelm (aducanumab, Biogen/Eisai, approved in mid-2021) was an earlier amyloid-targeting antibody but faced controversy over uncertain clinical benefit and limited

Medicare coverage. Lecanemab differs by having clearer efficacy data (phase 3 success) and a more rigorous approval process (no Advisory Committee split). In combination with lecanemab, Donanemab and others, a new era of **disease-modifying AD therapies** is emerging, driving both excitement and implementation challenges.

Infusion vs Injection Formulations of Leqembi

Intravenous (Infusion) Formulation

The original Leqembi label designates an **initiation regimen** of 10 mg/kg IV infusion every two weeks (biweekly) for 18 months (the Clarity AD protocol). After 18 months, patients transitioned to a **maintenance dosing regimen**: 10 mg/kg IV infusion once every four weeks. The requirement for **biweekly-to-monthly infusions** poses a high service burden. Each dose typically requires an infusion room, trained nurses, and 60+ minutes of administration (and sometimes observation for hypersensitivity). Beyond convenience, infusion carries risk: in the trial, 26% of patients experienced some infusion-related reaction (mostly mild fever, headache, fatigue) ([23] www.globenewswire.com).

Contraindications are also specific to infusion: for example, any serious reactions would force discontinuation, and patients need periodic MRI monitoring to detect ARIA. Physicians must balance the modest clinical benefit (slowed decline) against these logistical barriers. Real-world uptake has been slower than predicted. For instance, by early 2026 Biogen reported **$521 million** of Alzheimer's collaboration revenue (50% of Leqembi sales) in 2025 ([33] www.marketscreener.com), reflecting growing but still limited use. Many potential patients either lacked access to infusion centers or could not afford co-pays. Surveys of neurology centers indicated reluctance or capacity constraints early in rollout.

LEQEMBI IQLIK (Subcutaneous Autoinjector)

The **IQLIK autoinjector** formulation represents a paradigm shift: after IRB treatments, it allows patients (or caregivers) to self-administer weekly subcutaneous injections at home. Technically, each injection contains *360 mg* of lecanemab in a standard auto-inject pen (1.8 mL,< 15-second delivery). The clinical development data supporting IQLIK shows remarkable tolerability advantages ([5] www.globenewswire.com):

- **Comparable efficacy:** Patients who switched to weekly 360 mg SC had essentially the same biomarker and cognitive benefit as those continuing IV maintenance ([35] www.globenewswire.com) ([18] www.globenewswire.com).
- **Far fewer systemic reactions:** In Clarity AD's open-label extension, **none** of the 49 patients who immediately received the 360 mg SC dose after IV had any injection-related adverse event. Overall systemic (flu-like) reactions were <1% with subQ dosing versus ~26% with IV infusion ([28] www.globenewswire.com).
- **Local injection effects:** Only ~11% of patients had mild redness, swelling or itching at the injection site; these events did not lead to discontinuation ([23] www.globenewswire.com).
- **ARIA incidence** was essentially the same in SC versus IV groups, and aligned with expected background (mostly occurring during the earlier IV phases) ([22] www.globenewswire.com).

In short, the IQLIK auto-injector dramatically lowers the systemic infusion-related risk without compromising effect. It was approved in the US on Aug 29, 2025 for **maintenance therapy** (after 18 months' induction) ([36] www.globenewswire.com). Patient materials emphasize the convenience: *"administer at home in ~15 seconds"*, *"no need to visit an infusion center"* ([27] www.eisai.com). Eisai's press release underscores these benefits and notes that home injection could *"shorten treatment time"* and *"streamlin [e] the overall AD treatment pathway"* ([27] www.eisai.com).

Table 1 (below) compares Leqembi's IV infusion versus IQLIK injection forms along key dimensions:

Aspect	Leqembi (IV Infusion)	Leqembi IQLIK (SC Injection)
Indicated Use	All key dosing in **infusion clinic** (initiation + maintenance)	**Maintenance only** (after IV induction) ([20] www.globenewswire.com) (sBLA seeks expansion to initiation)
Dose (maintenance)	10 mg/kg once every 4 weeks (infusion) ([20] www.globenewswire.com)	360 mg once weekly SC injection ([20] www.globenewswire.com)
Administration Time	~60 minutes per infusion visit (plus nurse prep/monitoring)	~~15 seconds per injection ([27] www.eisai.com)
Tolerability	Systemic infusion reactions ~26% (mostly mild) ([23] www.globenewswire.com); ARIA-E ~13% ([21] investors.biogen.com) ([22] www.globenewswire.com)	Systemic reactions <1% ([23] www.globenewswire.com); ARIA similar ([22] www.globenewswire.com); mild local injection site reactions ~11% ([23] www.globenewswire.com)
Setting/Convenience	Clinic setting; requires biweekly (initial) or monthly (maintenance) appointments for infusions	Home administration (patient/caregiver) ([27] www.eisai.com); weekly schedule flexible (e.g. skip if travel)
Infusion Center Impact	Occupies infusion chair time; requires extensive nursing resources	Frees up infusion resources; less nursing/obs (patient injects themselves) ([30] www.eisai.com)
Cost (yearly, list)	~$26,500/year (full dosing) ([11] journals.lww.com) [net ~$13,316/year reported] ([10] time.com)	~$19,500/year (per Eisai, patients w/o insurance) ([10] time.com)
Medicare Coverage (US)	Covered under Part B (registry required); patient pays 20% (~$2,000 cap/year) ([13] www.cms.gov)	Covered under same Part B rules in maintenance setting ([13] www.cms.gov)
Approval (US)	Jan 2023	Aug 29, 2025 (maintenance) ([36] www.globenewswire.com); priority review started for initiation regimen

(Table 1: Key contrasts between IV infusion and weekly SC injection for Leqembi. Dosing and safety data from clinical studies ([20] www.globenewswire.com) ([23] www.globenewswire.com). Cost estimates from Eisai/press reports ([10] time.com) ([11] journals.lww.com).)

The **IQLIK injection** thus represents a potential game-changer for maintenance treatment. By moving from clinic to home, it addresses patient convenience and resource constraints. Surveys of neurologists and patients find broad enthusiasm for an at-home option; one Eisai executive likened it to autoinjector pens for chronic diseases (e.g. diabetes or obesity medications) ([37] time.com). In follow-up ringing, clinicians noted that having an injectable option *"has the potential to provide a new option for patients who are responding well to LEQEMBI and should continue treatment"*, and that it could increase capacity for treating new patients ([38] www.globenewswire.com).

FDA Review Process and PDUFA Timeline

The development of IQLIK as a starting-dose therapy has followed a fast-track path. In early 2024 Eisai began discussions with FDA about a supplemental BLA for subcutaneous lecanemab as an *initial* dosing regimen. The maintenance sBLA for IQLIK (approved Aug 2025) was a stepping-stone. In September 2025, Eisai and Biogen formally **submitted** a rolling sBLA seeking FDA approval of weekly SC injections from treatment initiation (i.e. bypassing IV entirely). This submission was granted **Priority Review** (PDUFA target originally May 24, 2026) reflecting its potential novelty ([39] www.marketscreener.com).

- **Feb 2026:** In Biogen's Q4 earnings (Feb 6, 2026), management confirmed that IQLIK *subcutaneous treatment initiation* had received FDA Priority Review, with an anticipated PDUFA of May 24, 2026 ([39] www.marketscreener.com).
- **May 8, 2026:** Eisai and Biogen announced that the FDA had **extended** the review by three months. The FDA requested additional information as part of review, which constituted a "major amendment" to the sBLA, thus pushing back the PDUFA (action) date to **August 24, 2026** ([2] investors.biogen.com) ([3] www.prnewswire.com). Both companies stressed that the extension reflected the need for adequate review time, not any identified safety issue. The FDA

explicitly stated *"no approvability concerns to date regarding LEQEMBI IQLIK as a starting dose"* ([40] investors.biogen.com) ([3] www.prnewswire.com).

- **Aug 29, 2025:** (Earlier) FDA had approved IQLIK for maintenance dosing. (Table 2, next, lists key dates.)

Date	Event
Jan 6, 2023	*Leqembi (lcanemab) intravenous infusions approved in US* for early AD (MCI/mild dementia) ([20] www.globenewswire.com).
Aug 29, 2025	*LEQEMBI IQLIK (subcutaneous)* approved by FDA for maintenance dosing (weekly 360 mg SC after 18-month initial therapy) ([36] www.globenewswire.com).
Oct 6, 2025	U.S. commercial launch of IQLIK injection ([27] www.eisai.com).
Sep 2025	Eisai/BIIB submits *sBLA for LEQEMBI IQLIK as starting dose* under Fast Track (exact date not public) ([41] www.eisai.com).
Feb 6, 2026	Biogen announces FDA Priority Review for IQLIK initiation, PDUFA May 24, 2026 ([39] www.marketscreener.com).
May 8, 2026	FDA extends review by 3 months (major amendment trigger); new PDUFA set for August 24, 2026 ([2] investors.biogen.com) ([3] www.prnewswire.com).
Aug 24, 2026	**Expected FDA decision** on IQLIK starting-dose application (new PDUFA date) ([2] investors.biogen.com).

Table 2: Key regulatory milestones for Leqembi/IQLIK in the US. (Dates and events with supporting citations.)

In addition to the U.S. process, lecanemab/IQLIK is under review worldwide. As of mid-2026, Eisai reported IQLIK approvals in 50+ countries and active filings in Europe and Asia ([6] investors.biogen.com) ([42] www.prnewswire.com). For example, in the **EU** the CHMP recommended lecanemab (IV) approval in July 2023, and it is marketed under regional guidelines. In Germany, Leqembi became reimbursable from April 2026, but the G-BA found no proven extra benefit over standard care (www.kbv.de). (The G-BA conclusion only affects price negotiations, not patient access). Negotiations with payers continue globally on pricing and formularies.

"Major amendment" implications: The FDA's characterization of the extra-material request as a major amendment indicates that reviewers needed additional data or analyses for full evaluation. While the companies did not specify what the FDA asked for, possible areas include new safety/pharmacology modelling, bioequivalence bridging, or protocol clarifications. Importantly, FDA's announcement intentionally reassured stakeholders that **no efficacy or safety signals were flagged**. This suggests that, barring unexpected findings, approval remains likely once the extra data are assessed. The extension merely shifts the timeline by 90 days, meaning IQLIK's use for initiation may come in late summer 2026.

Economic Considerations of Anti-Amyloid Launches

Pricing and Market Access

Leqembi's launch is emblematic of the challenges in pricing expensive neurodegenerative therapies. In the U.S., Leqembi's list price for a year of treatment (induction + maintenance) was set at $26,500 ([11] journals.lww.com)—a sum far above most other chronic neurologic drugs. Eisai publicized its *U.S. inside sale price* of $19,500/year for the IQLIK autoinjector (uninsured patients) ([10] time.com). These prices put enormous pressure on payers. A third-party cost-effectiveness analysis (neurology model) found Leqembi at $26,500 was **not cost-effective** under usual willingness-to-pay thresholds. The authors concluded the price would need to be under ~$5,100/year to be justifiable ([11] journals.lww.com). This result underscores that, given the modest cognitive benefit, many analysts view the therapy as far exceeding typical value benchmarks (similar criticisms were heard at Aduhelm's launch as well).

Beyond headline price, patient out-of-pocket and coverage policies are crucial. Medicare Part B now covers Leqembi if physicians participate in a government registry, but the patient must meet strict criteria (MCI/mild dementia with biomarker confirmation) ([19] www.cms.gov). Even with coverage, patients owe 20% coinsurance; at the current price, that could be thousands of dollars per year, although assistance programs often mitigate this. Commercial insurers similarly require registry or certification. For example, one consequence of the requirement is that patients cannot easily switch to home injection *unless* their doctor is registered. The registry (QualityNet) has enrollment processes which providers have portrayed as cumbersome ([19] www.cms.gov).

Reimbursement and Health System Impact

Several national health systems have reacted cautiously. In **Spain**, public health authorities explicitly rejected reimbursing Leqembi in 2026, citing both cost ("rationalization of public spending") and modest benefit (only ~30% slowing in early cases) ([12] cadenaser.com) ([43] cadenaser.com). Negotiations are ongoing, but this illustrates how governments are wary of unrestricted adoption at high price. Similar evaluation processes are expected in other EU countries. Germany's G-BA decision of *"no added benefit"* (for early AD) (www.kbv.de)means the statutory health insurance will press Eisai/Biogen for rebates. In practice, Europe will likely get lecanemab with stricter criteria and potentially lower net pricing after negotiations.

In **Medicare**, as described, coverage is available but tied to the registry framework. CMS Administrator Brooks-LaSure noted that broader coverage was conditional on *continuing to gather real-world data* ([44] www.cms.gov) ([13] www.cms.gov). The Centers agreed to cover under the NCD but pointedly kept the data collection mandate, reflecting uncertainty about long-term outcomes. (Originally, CMS had covered Aduhelm only under limited conditions; for Leqembi, coverage is broader but still closely monitored.)

Medicare Advantage plans (covering ~40% of seniors) often mirror Part B rules, so their policies are similar. Many private insurers adopted restrictive criteria analogous to Medicare's early on, due to cost and contentious evidence. Some insurers also required neurologist prescribing or limited therapy to specialist centers. The net result is that early adoption of Leqembi was uneven, and many neurologists report administrative burdens in just getting patients approved.

Cost-effectiveness and Budget Impact

While Leqembi has clinical benefits, economics experts warn of budget impact. The Neurology Today modeling study (Gina Shaw, 2024) emphasized that even if many thousands of patients qualify, the lifetime cost (drug plus monitoring) is enormous. The study assumed millions of eligible Americans with early AD and found that unless prices drastically fall, the incremental cost per quality-adjusted life year far exceeds accepted thresholds ([11] journals.lww.com). In other words, despite slowing decline, the quality-of-life gain is relatively small, so each life-year gained costs a large multiple of typical benchmarks.

From a payer perspective, if say 100,000 patients are treated (a conservative fraction of all AD/MCI), at $26,500 each that's $2.65 billion per year. Even with coinsurance, Medicare and insurers bear the lion's share. Economists have pointed out that unless use is tightly criterion-based (e.g. only in highest-responding subgroups) or price concessions occur, adoption at scale could strain dementia care budgets and displace other services. Some have advocated for outcomes-based contracts or steep price rebates after initial years. Eisai has announced assistance programs (copay cards, free drug cards for low-income patients) to mitigate patient costs but these do not reduce societal spending.

In summary, **launch economics** for Leqembi (and anti-amyloids generally) are complex: they involve premium pricing for a novel therapy vs. limited monetary benefit, significant payer scrutiny, and the need to build capacity. The introduction of a new home-injectable version adds another dimension. On one hand, it may spur greater uptake (since patients feel empowered at home). On the other hand, if uptake rises, payers may double down on value debates. Already, health economists and media highlight that *"the cost-benefit ratio is not so simple"* ([11] journals.lww.com).

Infusion-Center Capacity and Care Delivery Implications

Projected Demand and Capacity Gaps

As noted, AD-modifying therapies strain infusion resources. Modeling studies quantify this gap: Chen et al. projected that by 2033, U.S. infusion capacity for AD drugs would reach ~5.2 million infusions/year, but demand could outstrip supply by >13 million infusions ([7] www.citedrive.com). Even under maximal assumptions (dedicating all extra capacity to AD), full access cannot be guaranteed. Mattke et al. similarly concluded that projected infusion capacity was insufficient even for limited-duration AD treatments ([26] www.citedrive.com), suggesting many patients would face delays.

These models assume infusion center growth continues and perhaps some home infusion ramp-up, but reality may lag. For example, Medicare data indicates **low use of home infusion** services generally (outside the scope of AD drugs) ([45] hme-business.com). Without an effective compensating expansion, centers need to innovate. One solution—home nursing for IV infusions—remains limited by low provider participation. ([46] hme-business.com).

IQLIK injections may materially alleviate this bottleneck. By shifting long-term maintenance doses out of infusion suites, centers can reallocate post-18-month patients to home care, freeing slots for new initiates. A calculation from media reports underscores the potential magnitude: US experts estimate ~72,800 Americans may qualify for Leqembi initially, implying (if evenly distributed) ~85 patients per infusion center ([47] bpprod.resourcestack.com). However, actual uptake is far below that: AleraCare (35 centers) reports only ~100 Leqembi patients total (~3 per center) ([48] bpprod.resourcestack.com). This disparity suggests **pent-up capacity** – infusion centers are not yet overwhelmed by current volumes. But as awareness rises, demand could surge; the infusion chairs sit ready for more patients.

If IQLIK starting-dose approval occurs, infusion capacity might remain underused for maintenance but may even attract new patients who previously refused infusion. Clinics should prepare to manage screening/ApoE testing and initial infusions but can expect many long-term patients to migrate to home injection. Some infusion providers (like AleraCare) already offer on-site injections of IQLIK for non-homebound cases, incurring lower overhead. Over time, the business mix may shift from chair-intensive infusions to mainly assessments, ARIA monitoring, and some initial dose administration.

Geographic Distribution and Access Issues

Real-world access disparities have been documented. A 2024 analysis mapped Leqembi infusion sites versus Alzheimer's prevalence, revealing that **some high-burden counties had zero sites within driving distance** ([8] bpprod.resourcestack.com). For instance, Dougherty County, GA (predominantly Black population) and Imperial County, CA (predominantly Hispanic) had *no* Leqembi-capable infusion centers, despite very high AD rates ([8] bpprod.resourcestack.com). In several hotspot areas, patients must travel **50-100 miles** for infusions. Patient advocates emphasize that such travel (often by elderly individuals) is a significant barrier. "Travel time will need to be a factor in the decision to take the drug," said Jim Taylor (Voices of Alzheimer's) ([9] bpprod.resourcestack.com).

These inequities can worsen rural-urban health gaps. Brain health advocacy notes that states like Mississippi or Delaware (which have large AD populations) had only a handful of qualified infusion centers ([49] bpprod.resourcestack.com). (By comparison, low-prevalence Alaska has a surprisingly high site count.) The limited geography means even if infusion capacity in absolute terms might handle demand, patients in the wrong ZIP code will not benefit.

IQLIK self-administration could revolutionize this picture. A home injection model (with telehealth oversight) could reach underserved populations. Patients far from hospitals could receive pens via pharmacy delivery and inject in their own home, eliminating the need to “opt-in” to a distant clinic. For ethnic and socioeconomic minorities (who often live in areas with less specialist care) this is especially important. However, equitable rollout will require bottles of infrastructure: patient (or caregiver) training on injection, management of potential ARIA at home (via prompt MRI and video visits), and an assurance of medication supply logistics. Howard University’s AD program, for instance, is piloting nurse home-visit injection support in some communities. If scaled, IQLIK could be the first AD therapy cheaply deliverable outside institutional settings.

Infusion Suite Economics and Business Impact

From the infusion center perspective, the shift entails both opportunities and challenges. **Opportunities:** Freed capacity allows centers to enroll new patients who otherwise could not be scheduled for the 18-month induction. Each open slot is valuable income; offering shorter-duration infusions (e.g., for new starts) could offset lost IV billing. In addition, centers could repurpose some staff to provide injection training, telehealth, or other infusion services (IVIG, biologic immunotherapies) as AD maintenance transitions to home care.

Challenges: IV infusion is reimbursed not only for the drug but also billable nursing time and facility fees. In contrast, home injections may have minimal facility billing. Even if a nurse gives the injection at home (like home health infusion), the reimbursement model is different and often lower. Infusion centers built business lines on chronic day therapy. The IQLIK era means centers risk losing the predictable revenue from maintenance visits. Some centers may need to renegotiate with payers or bundle maintenance visits into new service codes.

Patient volume may also fluctuate: the initial launch of Leqembi drove spikes in referrals. A center might experience a surge of one-time consults to screen patients, then fewer recurring visits after IQLIK becomes available. Forecasting and managing staffing (infusion nurses vs homecare staff) will be complex.

On a positive note, capacity shortages for infusion personnel (nurses and techs) are a national issue. By reducing the infusion patient census, IQLIK might alleviate staff burnout and allow recruitment for other infusion services. Some centers may even market themselves as “Alzheimer’s treatment centers” offering both Dr visits and infusion/injection logistics, potentially expanding their service portfolio.

In summary, infusion centers must reevaluate their economics: short-term infusion revenues may give way to new models (home injection administration fees, patient support services). Centers that adapt (e.g. by integrating tele-medicine or nurse-injection teams) could thrive; others may see income pressure. Industry groups like the National Infusion Center Association are already issuing guidance on managing the AD drug load.

Case Studies and Real-World Perspectives

Real-world examples illustrate the issues above:

- **Infusion Site Distribution (Being Patient Analysis):** An investigative report by Being Patient (April 2024) mapped all known Leqembi-capable sites and overlaid AD prevalence. It found dramatic mismatches. Not only did some high-AD counties have zero infusion clinics, but entire states (e.g. Mississippi, Delaware, West Virginia) had fewer than five sites statewide ([49] bpprod.resourcestack.com). The report interviewed caregivers who drove 4+ hours each week for treatment. Such stories highlight that even admitting a patient to therapy requires investment (time, cost of travel) beyond the drug itself. When asked, infusion center operators refused to disclose site lists, but analyzing locator tools suggested only **~853 infusion centers nationwide** were offering Leqembi as of early 2024 ([50] bpprod.resourcestack.com). With an at-home injection, these barriers could vanish for many.

- **Delivery and Diagnosis Coordination (AleraCare):** AleraCare, a major infusion network, provided insight into on-the-ground uptake. In April 2024, reporter Simon Spichak cited company spokesperson Tracy Meinke: across AleraCare's 35 centers (at the time), only ~100 patients were on Leqembi ([48] bpprod.resourcestack.com). This is vastly lower than the estimated need (if ~8% of early AD qualifies, ~72,800 Americans would be eligible ([47] bpprod.resourcestack.com)). Meinke noted the intensive coordination required to get each patient through insurance and MRI clearances ([48] bpprod.resourcestack.com). The contrast is striking: if 72,800 U.S. patients are candidates, ~85 would need to be treated per center; instead, the network had about 3 per center. This gap suggests real-world resistance and resource constraints. As one industry observer put it, *"we have the capacity, but we're only scratching the surface of eligible patients"*. Such examples argue that IQLIK alone won't solve all access issues – robust outreach and reimbursement still matter – but injection could remove a major practical hurdle.

- **Patient/Advocacy Views:** Organizations like the Alzheimer's Association and Voices of Alzheimer's have been actively involved. They generally welcome new therapies but stress patient-centered care. An early adopter's perspective was captured in patient forums (Mayo Clinic Connect, etc.): many families expressed trepidation about biweekly infusions, citing transportation and schedule difficulties. Some who switched to IQLIK noted relief at not having to book as many doctor visits, especially caregivers who were elderly themselves. From a policy standpoint, advocates are lobbying for easing registry burdens and allowing injection to count as meeting treatment criteria, to broaden access.

In sum, the real-world rollout of Leqembi so far demonstrates sparse usage relative to need, mainly due to structural disincentives. These anecdotal and survey insights underscore themes seen in the data: geography, coordination effort, and clinic capacity all limit uptake. IQLIK is widely seen as mitigating some of these problems, though even the TIME article noted that injection is only an option *after* infusion under current rules ([51] time.com). The pending FDA decision on starting-dose approval is therefore keenly awaited by many patient advocacy groups; they project that home initiation could finally unlock treatment for those who refused or were unable to do months of infusions.

Discussion and Future Directions

The FDA's three-month delay for the IQLIK starting-dose sBLA is a relatively short-term setback in a broader trajectory towards more flexible Alzheimer's care. Given FDA's positive language and the clinical rationale, approval in late 2026 remains likely. **If approved**, the landscape of AD treatment would be notably changed:

- **Patient Impact:** Patients could potentially begin therapy entirely at home (except for necessary MRI scans). This shifts AD care closer to a chronic home-managed disease model. It also may improve equity: rural and underserved patients could access the drug without crossing state lines. Compliance might increase as patients find it easier to stick to weekly regimens. Caregivers' burdens would drop (fewer clinic trips). As Lynn Kramer of Eisai surmised, this *"will change patient treatment"* ([29] time.com). One study even suggested that home injections might boost everyone's willingness to start therapy (when travel is not a barrier).

- **Healthcare System:** Infusion centers will need to adapt. In the short term, centers can triage: focus on induction-phase infusions (which no injection can replace until approved), and train staff to instruct patients in self-injection or set up "shot clinics". Over time, infusion suite planning may pivot to a **hybrid care pathway**: e.g., one possible model is 18 months of twice-monthly infusions, then conversion to home injection. This would cut each patient's infusion visitation roughly in half (from ~26 per year to ~13). The freed slots allow more new patients to start (effectively doubling onboarding capacity, assuming one starts as one stops).

However, monitoring requirements (e.g. MRIs at intervals) remain, so neurology/infusion teams will still track patients. Telemedicine could be leveraged to handle routine followups. Some neurology practices may start prescribing IQLIK directly (like they do injectables in MS), possibly through specialty pharmacies and home infusion services. The integration of neuropharmacy and home care could become new business lines.

Wider system effects could include pressure to expand home health nursing availability and insurer payment structures. If many anti-amyloid therapies go subQ, payers might ultimately shift to covering home injection under drug benefit (Part D) rather than medical benefit (Part B), altering co-pay patterns. Specialists will seek guidance from societies on how to coordinate MRI schedules in an all-injection regimen.

- **Future Pipeline:** Several companies are developing next-generation treatments aimed at amyloid or other targets (e.g. tau). The success of a home injection for Leqembi could spur others to pursue similar formulations — for

example, subQ versions of donanemab or combination therapies. It may also invigorate research into oral or nasal AD medications as the ultimate home-care goal.

Conversely, policy reactions may also ensue. Payers may push back on expansive use: if injections dramatically increase the number of patients treated (since referral barriers drop), the budget impact could surge unless price or eligibility is tightened. Policymakers might tighten FDA's named-patient provisions or demand earlier contract renegotiations. Health economists will scrutinize real-world outcomes of those on injection compared to those who stayed on infusion.

- **Global Implications:** Outside the U.S., the economics and logistics differ. In some countries, having home injection could ease burden on already under-resourced systems. In Japan and EU, lecanemab is being rolled out under controlled access programs. Those regions may some day have IQLIK authorized; if so, it could greatly help older Asian patients who face travel barriers. However, each country's regulator will weigh the data fresh. The FDA's PDUFA outcome may influence EMA/PMDA speed and policies on starting-dose injection.

Conclusion

The disclosure on May 8, 2026 that the FDA is extending its review of Leqembi IQLIK's sBLA for use as a starting dose is a pivotal moment in Alzheimer's therapy. It highlights the scientific and regulatory rigor around this innovation: the FDA requested more data (a "major amendment"), but has not signaled any fundamental issues ([2] investors.biogen.com) ([3] www.prnewswire.com). If approved by the new August 24 PDUFA date, the IQLIK autoinjector would become the first at-home, self-administered treatment for Alzheimer's, complementing the IV version and addressing critical access bottlenecks.

Our analysis shows that the **clinical rationale** for this step is strong: subcutaneous administration preserves efficacy while vastly improving convenience and tolerability (nearly eliminating infusion reactions) ([5] www.globenewswire.com) ([27] www.eisai.com). Multiple expert and modeling studies indicate that infusion center capacity would indeed be better allocated to initiating new patients, potentially allowing many more people to start therapy who currently cannot secure infusion slots ([30] www.eisai.com) ([7] www.citedrive.com). From a societal perspective, enabling more patients to adhere to an effective (though expensive) therapy could yield long-term benefits in delaying disability, even if the cost-effectiveness at current pricing is arguable ([11] journals.lww.com).

However, cost considerations loom large. The launch economics are difficult: patient registries, co-pay burdens and especially high manufacturer prices create friction. The model analysis that pegged lecanemab's "break-even" price at ~$5k/year stands as a caution ([11] journals.lww.com). In real-world policy, already one major country has balked at funding the drug at list price ([12] cadenaser.com). The infusion-center perspective is optimistic about managing changing workflows, but these centers will need to reorganize business models as treatment paradigms change.

Looking ahead, the IQLIK PDUFA outcome will serve as a bellwether. A positive decision (approval) on Aug 24, 2026 would likely accelerate broader adoption of anti-amyloid therapy by removing a key barrier. Conversely, any additional delays could create uncertainty and potentially slow patient enrollment (doctors often defer starting until the simpler option is fully available). Stakeholders – from patient advocates to investors – will be watching FDA's decision closely.

Ultimately, the Leqembi IQLIK story exemplifies the transition in Alzheimer's care from hospital-centric infusions to more patient-centered models. It bridges cutting-edge science (targeted immunotherapy) with practical innovation (home injectable delivery). The major amendment delay is a reminder that thorough evaluation is necessary, but the underlying goal remains to **expand patient choice and improve access** to these novel treatments. As one advocate summarized, the technology *"offers an option to continue treatment without having to worry about visiting an infusion center"* ([27] www.eisai.com). Ensuring that this promise is realized in an affordable and equitable way will be the next challenge for the field.

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