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April 2026 Edition

In April: the FDA approved the first oral GLP-1 pill and the first gene therapy for genetic hearing loss, CMS finalized the CY 2027 Medicare Advantage and Part D rule, and the most significant drug prior authorization rulemaking in years opened for public comment.

Each item below is a compressed briefing on one policy development: what changed and what it means for your team right now. No filler. No 30,000-foot commentary. If it is in here, it has a direct line to formulary position, reimbursement rates, or patient volume.

IN THIS EDITION

FEDERAL

FDA APPROVALS

FDA Approves Foundayo (Orforglipron): First Oral GLP-1 Pill for Obesity

Lilly's once-daily pill approved April 1; self-pay starting at $149/month via LillyDirect

Update: The FDA approved Eli Lilly's Foundayo (orforglipron) on April 1, 2026 for adults with obesity or overweight with weight-related comorbidities -- the first oral small molecule GLP-1 receptor agonist that can be taken any time of day without food or water restrictions. Foundayo launched immediately via LillyDirect with shipping beginning April 6 and broad retail pharmacy availability shortly after. Self-pay pricing starts at $149/month for the lowest dose; eligible commercial patients may pay as little as $25/month with the Lilly savings card. Medicare Part D patients can access Foundayo at $50/month beginning July 1, 2026 through the GLP-1 Bridge.

Industry Impact: The first oral GLP-1 for obesity reshapes the competitive landscape for Wegovy and Zepbound and forces immediate payer formulary decisions on step therapy, prior authorization criteria, and tiering. The LillyDirect launch model also tests whether manufacturer-direct distribution can bypass traditional PBM/specialty pharmacy channels at scale. Payers should expect significant patient demand and utilization management pressure immediately.

FDA Approves Otarmeni: First-Ever Gene Therapy for Genetic Hearing Loss

Regeneron's one-time therapy for OTOF-related deafness approved April 23; offered free in the U.S.

Update: The FDA granted accelerated approval to Regeneron's Otarmeni (lunsotogene parvec-cwha) on April 23, 2026, the first and only gene therapy for severe-to-profound hearing loss caused by variants in the OTOF gene. Approval was based on the

CHORD trial, in which 80% of participants met or exceeded the primary hearing endpoint and 42% achieved normal hearing with longer follow-up. Regeneron will provide Otarmeni free of charge to eligible U.S. patients. The therapy is administered as a single surgical intracochlear infusion. Approval was granted under FDA's Commissioner's National Priority Voucher program. OTOF-related hearing loss affects approximately 50 newborns per year in the U.S.

Industry Impact: The free pricing model is unprecedented for a gene therapy and immediately raises payer pathway questions around coding, site-of-care, and coverage-with-evidence-development requirements. Market access teams in the gene therapy space should closely monitor how CMS and commercial payers build coverage criteria for a zero-list-price one-time therapy -- this will set precedent for future gene therapy access decisions.

FDA Approves Auvelity for Agitation Associated with Alzheimer's Disease

First non-antipsychotic approved for dementia-related agitation; approved April 30

Update: The FDA approved Axsome Therapeutics' Auvelity (dextromethorphan HBr and bupropion HCl) on April 30, 2026 for the treatment of agitation associated with dementia due to Alzheimer's disease -- the first non-antipsychotic approved for this indication. Auvelity was previously approved for major depressive disorder in 2022. The approval was supported by the ADVANCE-1 trial, which met its primary CMAI endpoint, and the ACCORD-2 randomized withdrawal trial, which demonstrated significantly longer time to relapse versus placebo. FDA granted Breakthrough Therapy and Priority Review designations. Agitation affects up to 76% of Alzheimer's patients and Alzheimer's disease affects more than 7 million people in the U.S.

Industry Impact: Payers must now build Part D utilization management criteria for a new indication in an already-approved drug targeting a large and growing dementia population. Expect step therapy requirements relative to antipsychotics, prior authorization for on-label Alzheimer's agitation versus off-label antipsychotic use, and formulary positioning decisions across Medicare Part D and commercial plans immediately.

FEDERAL

DRUG PRICING & NEGOTIATION

Medicare GLP-1 Bridge Confirmed: $50/Month Flat Copay Starting July 1

CMS confirms eligibility criteria and $245/month manufacturer net price

Update: CMS confirmed in April 2026 the key parameters of the Medicare GLP-1 Bridge, a Section 402 demonstration launching July 1, 2026 through December 31, 2027 (extended from the original December 31, 2026 end date after BALANCE model Part D plan participation fell short). Eligible Part D beneficiaries with BMI 35 or higher, or BMI 27 or higher with qualifying comorbidities, can access Wegovy, Foundayo, and Zepbound (KwikPen) at a flat $50/month copay. Manufacturers agreed to a net price of $245/month. The Bridge operates outside standard Part D, meaning the copay does not count toward TrOOP or the annual out-of-pocket cap.

Industry Impact: The Bridge's confirmation creates immediate formulary and access strategy implications for GLP-1 manufacturers. The $245 net price and the Bridge's separation from Part D benefit flow require manufacturers to model novel rebate and net price scenarios. The Foundayo approval the same month adds a third covered drug to the Bridge, complicating payer utilization management and step therapy design.

IRA Cycle 3: Counter-Offers Active for First-Ever Part B Drugs

April was the key negotiation window for 15 selected Part B/Part D drugs; oncology included for first time

Update: April 2026 was the primary counter-offer submission window in the third IRA negotiation cycle (IPAY 2028). All 15 manufacturers confirmed participation by the February 28 deadline. This is the first cycle to include drugs payable under

Medicare Part B, extending federal price negotiation into oncology and physician-administered therapies for the first time. MFPs are due November 30, 2026, with negotiated prices taking effect January 1, 2028.

Industry Impact: Manufacturers of the 15 selected drugs are in active negotiations with CMS through Fall 2026. The inclusion of Part B drugs means oncology manufacturers, HOPDs, and physician practices must now model IPAY 2028 exposure for the first time. The Supreme Court's May 2026 denial of cert removed any remaining legal offramp -- engagement is the only viable posture.

IRA SCOTUS Petitions: Final Manufacturer Briefs Filed Before May Decision

AstraZeneca, Boehringer, BMS, J&J, Novo Nordisk, Novartis petitions pending cert decision

Update: In April 2026, manufacturers including AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, Novartis, and Novo Nordisk filed final briefs in their Supreme Court petitions challenging the IRA Medicare Drug Price Negotiation Program. The Supreme Court subsequently declined to hear the challenges in May 2026, leaving CMS authority fully intact.

Industry Impact: The April filing activity represented the final industry attempt to block the program through litigation. With cert denied in May, all manufacturers in current and future negotiation cycles must engage fully. The window for legal strategy as an alternative to negotiation engagement has closed.

FEDERAL

COVERAGE & PRIOR AUTHORIZATION

CMS Publishes CMS-0062-P: Electronic PA Requirements Extended to Prescription Drugs

FHIR-based API timelines proposed for first time for drugs; 72-hour standard / 24-hour urgent

Update: CMS published proposed rule CMS-0062-P on April 10, 2026, proposing to extend electronic prior authorization requirements to prescription drugs -- closing a gap left by the 2024 CMS-0057-F final rule, which covered only non-drug items and services. The proposed rule would require impacted payers (Medicare Advantage, Part D, Medicaid managed care, and QHP issuers on the FFE) to support FHIR-based electronic PA for drugs, establish 72-hour standard and 24-hour urgent decision timelines, mandate denial transparency, and publicly report PA metrics. If finalized, most requirements take effect October 1, 2027. Public comments are due June 15, 2026.

Industry Impact: This is the most consequential open rulemaking window for specialty drug access in 2026. Faster, standardized PA reduces time-to-therapy for high-cost specialty drugs. Manufacturers of biologics, oncology therapies, and Part B physician-administered drugs should be preparing comments now ahead of the June 15 deadline.

ACTION REQUIRED: JUNE 15 DEADLINE

Comment Period Closes: CMS Drug PA Proposed Rule (CMS-0062-P)

Comments must be submitted to regulations.gov before June 15, 2026

What to include: PA denial rates by drug class, time-to-therapy delays documented by indication, operational barriers to FHIR-based PA implementation, and data on patient harm resulting from delayed access. CMS has stated that comments addressing real-world access gaps carry direct weight in how it calibrates final decision timelines and transparency requirements.

Who should act: Manufacturers of biologics, oncology therapies, Part B physician-administered drugs, specialty drugs with high PA denial rates, and any manufacturer whose payer mix includes MA, Part D, or Medicaid managed care plans.

WISeR AI Prior Authorization Model: Provider Scrutiny Intensifies

AI-driven PA in traditional Medicare FFS active since January 1; OIG oversight pressure building

Update: CMS's WISeR (Wasteful and Inefficient Services Reduction) AI Prior Authorization Model has been active in traditional Medicare FFS since January 1, 2026. Throughout April, medical societies escalated complaints about erroneous denials and access delays for physician-administered drugs, and OIG oversight pressure continued to build. Senate legislation to restrict or repeal the model was introduced in late May 2026.

Industry Impact: AI-assisted PA in traditional Medicare FFS directly affects access timelines for Part B physician-administered drugs including biologics and oncology infusions. Manufacturers should monitor denial rate data by HCPCS code and engage medical society partners tracking WISeR's downstream access impacts. The legislative response in May signals the PA landscape will remain volatile through 2027.

FEDERAL

MEDICARE ADVANTAGE & PART D POLICY

CMS Finalizes CY 2027 Medicare Advantage and Part D Rule

IRA Part D redesign codified into regulation; Star Ratings updated; effective June 1, 2026

Update: CMS finalized the CY 2027 Medicare Advantage and Part D Final Rule on April 2, 2026, with the Rate Announcement following on April 6. The rule codifies the IRA's restructured Part D benefit and Manufacturer Discount Program framework into permanent regulation, implements the $2,100 annual OOP cap (indexed annually), updates Star Ratings by removing select measures and adding a new Depression Screening measure beginning with 2029 Star Ratings, and pursues a broad deregulatory agenda aligned with Executive Order 14192. The rule is effective June 1, 2026, with most provisions applicable to CY 2027 coverage. The Rate Announcement projects a net average increase in MA payments of 2.48%, or over $13 billion in additional payments to plans.

Industry Impact: Codification of the IRA Part D redesign into regulation makes the $2,100 OOP cap and Manufacturer Discount Program permanent features of the benefit structure -- no longer subject to annual subregulatory guidance. For specialty drug manufacturers, this cements the financial calculus favoring adherence for high-cost products. The Star Ratings changes shift relative weight toward survey-based and clinical outcome measures, creating new formulary positioning dynamics for plans optimizing their ratings.

RAPID Pathway Announced: FDA/CMS Joint Program for Breakthrough Device Coverage

Accelerated Medicare coverage to approximately 60-90 days post-approval; NTAP alternative pathway proposed for elimination

Update: CMS and FDA jointly announced the RAPID (Rapid Access Pathway for Innovative Devices) program on April 23, 2026, offering accelerated Medicare coverage for breakthrough-designated devices to approximately 60-90 days post-FDA approval. CMS simultaneously proposed eliminating the NTAP alternative pathway for inpatient payment add-ons.

Industry Impact: RAPID compresses the FDA-to-Medicare coverage lag, historically one of the most significant barriers for device market access. But the concurrent NTAP elimination proposal raises the evidentiary bar for inpatient add-on payments, partially offsetting the speed advantage for devices that depend on NTAP to bridge the coverage gap. Device manufacturers should model both pathways against their product's clinical profile and reimbursement strategy.

STATE

PBM REFORM & PHARMACY ACCESS

Tennessee FAIR Rx Act Passes Both Chambers

Anti-vertical integration PBM bill heads to governor; divestiture required by July 1, 2028

Update: Tennessee's FAIR Rx Act passed both legislative chambers on April 21, 2026, prohibiting entities from simultaneously owning a pharmacy, PBM, and insurer. The bill requires full divestiture of conflicting ownership structures by July 1, 2028 and was subsequently signed into law by the governor in May 2026.

Industry Impact: One of the most structurally aggressive state PBM interventions to date. Manufacturers distributing through PBM-owned specialty pharmacies in Tennessee must immediately begin assessing channel continuity planning through the 2028 divestiture deadline. The bill is a leading indicator for similar vertical integration restrictions advancing in other state markets.

Medicaid Work Requirements: 43 States Must Implement Under OBBBA

KFF confirms 43-state scope; 80 hours/month requirement; Nebraska first to enforce May 1

Update: A KFF analysis confirmed that 43 states are required to implement Medicaid community engagement (work) requirements of 80 hours per month under the One Big Beautiful Bill Act. Nebraska was the first state to enforce requirements beginning May 1, 2026. Coverage loss modeling was underway across all affected states in April as implementation planning accelerated.

Industry Impact: Medicaid volume erosion in behavioral health, infectious disease, chronic disease management, and primary care is the near-term market access risk. Manufacturers with significant Medicaid-dependent patient populations should model state-by-state beneficiary loss scenarios now, particularly in expansion states where coverage losses are projected to be highest.

Every item in this newsletter is a decision your team needs to make.

The CMS-0062-P comment window closes June 15. IRA Cycle 3 negotiations are active. The first oral GLP-1 just launched and payers are building formulary strategy right now. None of this waits for your next quarterly review.