

ACCESS REVIEW

The 3-month Access Review.

Nine focus areas, plus notable changes elsewhere: what the FDA, guideline committees, payers and states changed.

37
FDA ACTIONS*

7
GUIDELINE CHANGES†

3
POLICY CHANGES‡

18 FDA approval or new indication
◆ Guideline change
■ Policy change

	JULY	AUGUST	SEPTEMBER
● Autoimmune	7 Atacicept (Trutakna) · IgA nephropathy	24 Nipocalimab (Imaavy) · warm autoimmune hemolytic anemia 27 Brepocitinib (Lisraya) · dermatomyositis	
● Bone & joint		19 Garetoismab (Pasatru) · fibrodysplasia ossificans progressiva (FOP)	25 Zilurgisertib (Atebrioz) · FOP, a second option
● Cardiometabolic	15 Enlicitide (Lipfendra) · first oral PCSK9 inhibitor	27 Tirzepatide (Mounjaro) · cardiovascular risk, type 2 diabetes 31 ◆ ESC heart failure (Europe)	17 Finerenone (Kerendia) · CKD in type 1 diabetes 23 Insulin efsitora alfa (Onswik) · first weekly basal insulin
● Donation & transplant	27 RSV vaccine (Arexvy) · adds lung and kidney transplant	17 ■ OPTN: 7-day HIV and WNV testing for living donors	
● Neurological		5 Oveporexton (Orzeyful) · narcolepsy type 1 13 Florquinitalu F18 (Tauklarify) · tau PET for Alzheimer's 31 ◆ AAN/AHS migraine prevention	25 Tavapadon (Juvmo) · Parkinson's disease
● Oncology	10 Pembrolizumab + enfortumab vedotin · bladder 14 Gedatolisib (Revtorpyk) · PIK3CA wild-type breast 14 Selpercatinib (Retevmo) · RET+ tumors, full approval 16 ◆ ASCO breast surveillance 22 Zidesamitinib (Jideytrio) · ROS1+ lung 31 Lu 177 vipivotide (Pluvicto) · PSMA+ prostate, earlier	6 Vusolimogene (Tudriqev) · melanoma 13 Iberdomide (Zenbexus) · myeloma 25 Zanidatamab (Ziihera) · first-line HER2+ gastric 26 Daraxonrasib (Rasonque) · pancreatic	4 Camizestrant (Etcamah) · ESR1-mutated breast, blood test 9 Sevabertinib (Hyrnuo) · HER2-mutant lung 18 Imlunestrant (Inluriyo) · ESR1-mutated breast 23 Lirafugratinib (Lyrfhtu) · FGFR2 cholangiocarcinoma
● Rare disease	1 Exa-cel (Casgevy) · sickle cell and thalassemia, now ages 2–11	19 Pariglasgene (Genglycos) · GSD1a gene therapy 28 Rusfertide (Mimrylo) · polycythemia vera	3 Zilganersen (Zanvastro) · Alexander disease 11 Apitegromab (Isemyld) · SMA add-on 28 Tiratricol (Emcitate) · MCT8 deficiency
● Respiratory			7 ◆ ERS PAH update (Europe) 22 Sotatercept (Winrevair) · newly diagnosed PAH
● Vaccines		5 mRNA flu vaccine (mFLUSIVA) · adults 50+ 27 2026–27 COVID-19 vaccines · labels limited to 65+ and higher risk	2 ◆ AAP, AAFP, ACOG, IDSA respiratory schedule 23 ◆ CDC COVID-19 · all adults
● More care areas	24 Centanafadine (Simtriyo) · ADHD · Mental & behavioral	20 ◆ ACOG: opportunistic salpingectomy · Women's & maternal 27 Bictegravir/lenacapavir (Bixlenvo) · HIV · Infectious disease	
● U.S. health system	■ Jul 1 · Medicare GLP-1 Bridge · \$50 a month · through Dec 31, 2027 →		
	■ Sep 30 · GLOBE model final →		

See something we missed?

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* Novel FDA approvals, notable new indications and conversions to full approval in the focus areas. † New or fully revised guidelines and recommendations from major U.S. and international bodies; interim updates such as NCCN versions are not counted. ‡ Final federal actions with national reach that change who can get a therapy, or on what terms. All counts selected, not comprehensive.

Covers July 1 – September 30, 2026. Sources: FDA, CDC, issuing guideline bodies, CMS and HRSA/OPTN. Generic names first; listing is not endorsement.



ACCESS REVIEW

What moved, and what comes next.

Six changes to watch: which party moved, which hurdle moved, and the evidence the next party will need.

FDA

Is it safe and effective?

GUIDELINE COMMITTEES

Should it be used, and when?

PAYERS & STATES

Will it be paid for, and for whom?

CHANGE	PARTY · HURDLE	WHAT MOVED IT	NEXT PARTY NEEDS
ONCOLOGY Camizestrant (Etcamah) Sep 4, 2026	FDA ↑ An ESR1 mutation must be found by blood test during first-line therapy	Accelerated approval on a trial that switched therapy when ESR1 appeared in the blood, before the cancer progressed; blood test approved the same day	Payers and states: coverage of repeat blood testing during treatment, not a one-time test at diagnosis.
ONCOLOGY Selpercatinib (Retevmo) Jul 14, 2026	FDA ↓ Full approval for RET fusion-positive solid tumors of any type, ages 2+	Converted from accelerated to traditional approval after confirmatory data	Payers and states: broad genomic panels for every tumor type, since a single-gene test will not find RET.
VACCINES 2026–27 COVID-19 vaccines Aug 27 and Sep 23, 2026	FDA, then CDC ↑ FDA labels limited to 65+ and people with a risk condition ↓ CDC recommends vaccination for all adults	FDA strain selection in May; CDC guidance now marks where it goes beyond the label. ACIP has not met in 2026	Payers: without an ACIP vote there is no new no-cost mandate; insurers' voluntary pledge runs through 2027.
CARDIOMETABOLIC Insulin efsitora alfa (Onswik) Sep 23, 2026	FDA ↓ First once-weekly basal insulin for type 2 diabetes	Phase 3 trials against daily basal insulin in type 2 diabetes	Payers: formulary placement against daily basal insulins, and how weekly dosing fits insulin cost caps.
NEUROLOGICAL AAN/AHS migraine prevention Aug 31, 2026	Guideline committee ↓ Prevention recommended from 4 migraine days a month, or when migraine impairs function	Updated evidence review from the American Academy of Neurology and American Headache Society	Payers: prior authorization and step-therapy criteria written for older, higher thresholds.
U.S. HEALTH SYSTEM USPSTF restarted Sep 17, 2026	HHS ↓ Eight new members end a 17-month pause in screening recommendations	Appointments by the HHS Secretary, including oncology and GI specialists and a new chair	Payers: new USPSTF grades set which screenings the ACA requires at no cost; none have been issued yet.

↓ Lowers a hurdle for patients ↑ Raises a hurdle for patients

Next edition November 15. Access Review publishes on the 15th of every month. Its companion, **Advocacy Ahead**, looks three months ahead on the 1st. Both at ahis.org/access-review.