AHIS alliance for health implementation science

AUGUST – OCTOBER 2026
November 15, 2026 edition

ACCESS REVIEW

The 3-month *Access Review.*

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

40 FDA ACTIONS*

8 GUIDELINE CHANGES†

3 POLICY CHANGES‡

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

	AUGUST	SEPTEMBER	OCTOBER
Autoimmune	**24** Nipocalimab (Imaavy) · warm AIHA **27** Brepocitinib (Lisraya) · dermatomyositis		**15** Satralizumab (Enspryng) · thyroid eye disease
Bone & Joint	**19** Garetosmab (Pasatru) · FOP	**25** Zilurgisertib (Atebrioz) · FOP, ages 12+	
Cardiometabolic	**27** Tirzepatide (Mounjaro) · CV risk, type 2 diabetes **28** ◆ **ESC heart failure (Europe)**	**16** Finerenone (Kerendia) · CKD, type 1 diabetes **23** Insulin efsitora alfa (Onswik) · weekly basal insulin	
Donation & Transplant	**17** ■ **OPTN: 7-day HIV and WNV testing for living donors**		**30** ■ **CMS: organ procurement organization rule**
Neurological	**5** Oveporexton (Orzeyful) · narcolepsy type 1 **13** Florquinitau F 18 (Tauklarify) · tau PET **31** ◆ **AAN/AHS migraine prevention**	**25** Tavapadon (Juvmo) · Parkinson's	
Oncology	**6** Vusolimogene (Tudriqev) · melanoma **13** Iberdomide (Zenbexus) · myeloma **25** Zanidatamab + tislelizumab · HER2+ gastric **26** Daraxonrasib (Rasonque) · pancreatic	**4** Camizestrant (Etcamah) · ESR1+ breast **9** Sevabertinib (Hyrnuo) · HER2-mutant lung **11** Floretyrosine F 18 (Pixclara) · glioma PET **18** Imlunestrant (Inluriyo) · ESR1+ breast **23** Lirafugratinib (Lyrfigtu) · FGFR2 bile duct **24** Belzutifan + lenvatinib · kidney	**2** Pirtobrutinib (Jaypirca) · first-line CLL **7** Tucatinib (Tukysa) · HER2+ breast **8** Atezolizumab (Tecentriq) · stage III colon **14** Nogapendekin alfa (Anktiva) · bladder **16** Pembrolizumab (Keytruda) · TMB-high **19** Dostarlimab (Jemperli) · dMMR rectal **26** Talazoparib (Talzenna) · prostate **27** ◆ **ASTRO prostate radiation**
Rare Disease	**19** Pariglasgene (Genglycos) · GSDIa **28** Rusfertide (Mimrylo) · polycythemia vera	**3** Zilganersen (Zanvastro) · Alexander disease **11** Apitegromab (Isembyld) · SMA add-on **17** Rebisufligene (Fayuvi) · MPS IIIA **28** Tiratricol (Emcitate) · MCT8 deficiency	
Respiratory		**3** ◆ **ERS PAH update (Europe)** **21** Sotatercept (Winrevair) · newly diagnosed PAH	
Vaccines	**5** mRNA flu vaccine (mFLUSIVA) · ages 50+ **27** 2026-27 COVID-19 vaccines · 65+ and higher risk	**2** ◆ **AAFP, AAP, ACOG, IDSA respiratory schedule** **23** ◆ **CDC COVID-19** · all adults	
More care areas	**20** ◆ **ACOG: salpingectomy** · Women's & maternal **27** Bictegravir/lenacapavir (Bixlenvo) · HIV · Infectious disease		**9** Pritelivir (Hovilpri) · herpes · Infectious disease **15** ◆ **ACOG: menopause** · Women's & maternal **20** Bepirovirsen (Hibsago) · hepatitis B · Infectious disease
U.S. health system		■ **Sep 30** · GLOBE model final →	

See something we missed?

Scan the code or email **info@ahis.org**

* 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 August 1 – October 31, 2026. Sources: FDA, CDC, issuing guideline bodies, CMS and HRSA/OPTN. Generic names first; listing is not endorsement.

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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 **Dostarlimab (Jemperli)** Oct 19, 2026	**FDA** ↓ Accelerated approval for adults with stage II–III rectal cancer ↑ dMMR or MSI-H must be found by an FDA-authorized test	AZUR-1, a single-arm trial: 47% had a complete response lasting 12 months	**Payers and states:** mismatch repair testing at diagnosis, and coverage of follow-up in place of surgery.
Oncology **ASTRO prostate radiation** Oct 27, 2026	**Guideline committee** ↓ Shorter courses for all risk groups; five-session SBRT a standard option for many	Updated evidence review replacing ASTRO's 2018 guideline, as randomized trials matured	**Payers:** coverage and prior authorization for five-session SBRT, including intermediate-risk disease.
Respiratory **Sotatercept (Winrevair)** Sep 3 and Sep 21, 2026	**ERS, then FDA** ↓ ERS: add-on for intermediate- and high-risk PAH ↓ FDA: label adds recently diagnosed adults	Randomized trial evidence; ERS made no recommendation for low-risk PAH	**Payers:** prior authorization and step-therapy criteria written for use later in the disease.
Rare Disease **Rebisufligene (Fayuvi)** Sep 17, 2026	**FDA** ↓ One-time gene therapy for MPS IIIA in children whose development is preserved	Single-arm study, ages 2–5: cognitive scores against an untreated historical group	**Payers and states:** diagnosis early enough to qualify, and coverage terms for a one-time therapy.
Women's & Maternal **ACOG menopause guidance** Oct 15, 2026	**Guideline committee** ↓ If chosen, hormone therapy started before 60 or within 10 years of menopause; nonhormonal options reviewed	ACOG evidence review of hormone, nonhormonal and nonpharmacologic treatment	**Payers:** coverage of hormone and nonhormonal treatments, which ACOG calls critically important.
Donation & Transplant **Organ procurement rule** Oct 30, 2026	**CMS** ↓ High-performing organ procurement organizations may compete for more donation areas	Final rule revising the conditions for coverage, with organ tracking and faster decertification	**States and transplant programs:** smooth handovers when one organization takes over another's area.

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

Next edition December 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**.

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