

Arkansas Medicaid PAD Subcommittee Meeting Minutes

Date / Time:	September 09, 2026 12:00-1:00 PM Central		Location:	Teams webinar	
Chair:	Cindi Pearson, Pharm.D.		Reports:	Brooke Owens, Pharm.D. Prime Therapeutics	
Attendance		Panelist (voting members)		Panelist (non-voting members)	Organization
	X	Ashley Crawley, Pharm.D.	X	Ginny Yates, Pharm.D.	ATC
	X	Gabriella Douglass, Pharm.D.		Travis Gau, Pharm.D.	Empower
	X	William Golden, M.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Melissa Max, Pharm.D.		Jessica Lawson, Pharm.D.	CareSource
	X	Christopher Smith, M.D.	X	Ifeyinwa Onowu, Pharm.D.	CareSource
		Panelist (non-voting) Prime Therapeutics	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	Karen Evans, P.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Jeniffer Martin, Pharm.D.		Elizabeth Pitmann, J.D.	DMS director
	X	Lesley Irons, Pharm.D.	X	Ashley Guajardo	DHS pharmacy
	X	Linsey Gillam, Pharm.D.	X	Shane David, Pharm.D.	ADH advisor
	X	Alyson Greenwood, Pharm.D.			
	X	Brooke Owens, Pharm.D.			
		Allison Sweeney, Pharm.D.			
Call to order	Meeting held virtually by Teams webinar. A quorum was present, and the chair called the meeting to order at 12:00 pm. Voting members had no conflicts of interest except for Dr. Douglass had conflict of interest on the agenda item for GILEAD. Dr. Pearson and Dr. Owens did not have any conflicts.				
Public Comments	1. Maribel Borysyuk, PharmD—SANOFI TZIELD 2. Cecilia Ciarlo, MSN, APRN, FNP-BC—GENENTECH Wes Pierce, PharmD, BCPS, BCCCP—GENENTECH OCREVUS and TECENTRIQ 3. Augustus Billy, MD—OMEROS CORPORATION YARTEMLEA 4. Nancy Njuguna, BPharm, MBA—GILEAD TRODELVY				
Minutes	Motion to approve the JUNE 2026 DUR Subcommittee meeting minutes as presented was made by Dr. Golden; second by Dr. Crawley. All voting members present voted for approval of the minutes as written. Motion passed.				
PAD Monographs	JUNE DUR Subcommittee recommendations were submitted to the DUR Board during the JULY 15, 2026 meeting. Monographs were approved as presented, and the updated monographs were posted that day.				
General Monograph Updates	1. DATROWAY (datopotamab deruxtecan-dlnk) for injection Dr. Owens recommended the following changes to the current monograph: • Indications were updated on the monograph to match the package insert. • Clinical criteria modifications - fellowship trained oncologist - beneficiary meeting 18 years of age				

- does not have active or prior history of interstitial lung disease (ILD)/pneumonitis requiring systemic therapy
- has ECOG status of 0-3
- Under breast cancer, the indication was modified to include the beneficiary has a diagnosis of unresectable or metastatic, triple negative breast cancer and is not a candidate for PD-1/PD-L1 inhibitor therapy (e.g., PD-L1 negative or previously treated)

DISCUSSION:

No comment.

ACTION:

Motion to approve the changes as presented was made by Dr. Smith; second by Dr. Golden. All voting members present voted for approval. Motion passed.

2. KEYTRUDA/KEYTRUDA QLEX (pembrolizumab/ pembrolizumab and berahyaluronidase alfa-pmph) injection

Dr. Owens recommended the following changes to the current monograph:

- Indication for renal cell carcinoma was added to include used in combination with belzutifan, for the adjuvant treatment of adult beneficiaries with RCC with a clear cell component (ccRCC) at intermediate-high- or high-risk recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.
- New indication for triple negative breast cancer (TNBC) to include can be used in combination with sacituzumab govitecan-hziy for the first-line treatment of adult beneficiaries with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.
- Clinical criteria modifications
 - adult beneficiaries for MIBC patients

DISCUSSION:

No comment.

ACTION:

Motion to approve the changes as presented was made by Dr. Golden; second by Dr. Crawley. All voting members present voted for approval. Motion passed.

Updated Monographs presented as a consent calendar

1. OCREVUS (ocrelizumab) injection

Dr. Owens recommended the following changes to the current monograph:

- Indications were modified for treatment to include “except as noted:” Also added Relapsing-Remitting MS, in pediatric beneficiaries 10 years of age or older who weigh 25kg or more- note: not indicated for Ocrevus Zunovo
- Clinical criteria modifications
- beneficiary must be ≥ 10 years of age for relapsing forms of MS or meet the minimum age per FDA labeled package insert for other indications.
- The beneficiary has a confirmed diagnosis of a relapsing form of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS [RRMS] or secondary progressive MS [SPMS] with relapses) demonstrated by dissemination in space (DIS) and dissemination in time (DIT), except when lesions are present in ≥ 4 of the 5 characteristic CNS regions, in which case DIS alone is sufficient.

- Dissemination in space (DIS): MRI showing involvement of T2 lesions in ≥ 2 characteristic CNS regions (periventricular, cortical/juxtacortical, infratentorial, spinal cord, and the optic nerve [shown by MRI, VEP (visual evoked potential)/OCT (optical coherence tomography)]). No CSF is needed for DIS diagnosis may be confirmed by DIS alone when lesions are present in ≥ 4 of the 5 regions listed above
- Dissemination in time (DIT): development of lesions at different time points, shown by a new T2 lesion on follow-up MRI, the simultaneous presence of gadolinium-enhancing and non-enhancing lesions on a single scan, or a second clinical attack. CSF-specific oligoclonal bands (OCBs) or kappa free light chains (kFLC) can substitute for DIT
- The beneficiary has a confirmed diagnosis of primary progressive multiple sclerosis [PPMS] by the following:
 - ≥ 12 months of disability progression independent of clinical relapse; AND
 - 2 or more of the following must be met:
 - ≥ 1 characteristic T2 lesion in ≥ 1 typical CNS region (periventricular, cortical/juxtacortical, infratentorial, or optic nerve [shown by MRI, VEP, or OCT])
 - ≥ 2 T2 spinal cord lesions
 - CSF-specific oligoclonal bands or elevated kappa free light chain index (kFLC index ≥ 6.1)
- Clinical notes document both baseline number of relapses per year and expanded disability status scale (EDSS) score
- Clinical notes must document the beneficiary's baseline Expanded Disability Status Scale (EDSS) score
 - For RRMS, the beneficiary must have an EDSS score of 0 to 5.5.
 - For PPMS, the beneficiary must have an EDSS score of 0 to 8.0. Beneficiaries with an EDSS score greater than 6.5 must have documentation supporting the expected clinical benefit of treatment.
- The beneficiary's clinical presentation, imaging findings, and diagnostic testing are not better explained by an alternative diagnosis, and other disease mimics have been reasonably excluded
- Age-appropriate immunizations should be completed prior to initiating therapy in accordance with current guidelines
- Beneficiary has had an inadequate response or intolerance to any adequate prior disease-modifying therapy (e.g., a fumaric acid derivative) where inadequate response is defined as any of the following while on adequate therapy (≥ 3 –6 months of continuous therapy at the labeled dose, with documented adherence);
 - Clinical relapse (≥ 1 in the previous year)
 - New or enlarging T2 lesions on MRI, OR ≥ 1 gadolinium-enhancing lesion.
 - Confirmed disability progression

If the above criteria have not been met, detailed clinical rationale and supporting documentation demonstrating why Ocrevus is medically necessary as first-line treatment must be provided

OR

- The beneficiary has highly active or rapidly evolving severe RRMS, for which a prior disease-modifying therapy trial is not required, defined by either:
 - ≥ 1 relapse in the previous year AND ≥ 9 T2 hyperintense lesions or ≥ 1 gadolinium-enhancing lesion on brain MRI; OR
 - ≥ 2 disabling relapses in one year AND ≥ 1 gadolinium-enhancing lesion or a significant increase in T2 lesion burden versus a recent prior MRI
- For beneficiaries with PPMS, OCREVUS may be approved as first-line disease-modifying therapy

DISCUSSION:

No comment.

2. TECENTRIQ (atezolizumab) injection

Dr. Owens recommended the following changes to the current monograph:

- Indications were modified to add Muscle Invasive Bladder Cancer (MIBC)
- Clinical criteria modifications
 - drug must be prescribed by a fellowship trained oncologist
 - beneficiary must have an ECOG performance status of 0-3
 - MIBC was also added and included the drug is used as adjuvant treatment in adult beneficiaries with MIBC after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test

DISCUSSION:

No comment.

3. IMFINZI (durvalumab) injection

Dr. Owens recommended the following changes to the current monograph:

- Modified the indications for treatment to match the package insert
- Clinical criteria modifications
 - The drug must be prescribed by a fellowship trained oncologist
 - New bladder cancer indication was added in combination with Bacillus Calmette-Guérin (BCG) for adult beneficiaries with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC)

DISCUSSION:

No comment.

**4. TRODELVY (Sacituzumab govitecan-hziy) for injection
(Dr. Douglass abstained due to conflict)**

Dr. Owens recommended the following changes to the current monograph:

- Modified the indications for treatment to match the package insert
- Clinical criteria modifications
 - The drug is used as a single agent for first-line treatment of adult beneficiaries with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy

- The drug is used in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmpH for the first-line treatment of adult beneficiaries with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test
- The drug must be prescribed by a fellowship trained oncologist
- The metastatic urothelial cancer was removed and moved to the NCCN recommendation section with the following language. The drug is used as 2nd-line and subsequent-line monotherapy in beneficiaries with locally advanced or metastatic disease

DISCUSSION:

No comment.

5.TZIELD (teplizumab-mzwv) injection

Dr. Owens recommended the following changes to the current monograph:

- Indications were modified to include age down to one year of age or older for stage 2 T1D, and to delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D. This indication is approved under accelerated approval based on evidence of reduced C-peptide decline. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Limitations of use: There is limited evidence of safety and effectiveness in patients aged 45 years and older with Stage 2 T1D. Tzield is not effective as a disease modifying therapy in non-autoimmune dysglycemic conditions.
- Clinical criteria modifications
 - Drug must be prescribed by or in consultation with a fellowship trained endocrinologist
 - The beneficiary has been evaluated for active Epstein-Barr virus (EBV) and Cytomegalovirus (CMV) infection prior to initiation
 - The beneficiary-specific treatment plan and infusion schedule must be provided
 - Defined laboratory values were added for complete blood count and liver enzyme tests prior to the start of treatment.
 - The requirements for at least one relative with T1D was removed
 - Exclusions were modified to include beneficiaries that are immuno-compromised or have an active viral infection
 - Stage 2 T1D was modified to include a 30-, 60-, or 90-minute plasma glucose of ≥ 200 mg/dL during an oral glucose tolerance test (OGTT) as part of dysglycemia documentation options.
 - Stage 3 T1D criteria was added.
 - The beneficiary has a diagnosis of stage 3 T1D confirmed by documenting overt hyperglycemia as defined by one of the following: A 2-hour plasma glucose of ≥ 200 mg/dL during an oral glucose tolerance test OGTT, A fasting plasma glucose of ≥ 126 mg/dL, an HbA1c of $\geq 6.5\%$, a random plasma glucose of ≥ 200 mg/dL in a beneficiary with classic symptoms of hyperglycemia or hyperglycemic crisis; AND
 - Confirmation of one or more positive pancreatic islet cell autoantibodies: Islet cell autoantibody (ICA), Insulinoma-associated

antigen-2 autoantibody (IA-2A), Insulin autoantibody (IAA), Zinc transporter 8 autoantibody (ZnT8a), Glutamic acid decarboxylase 65 (GAD65) autoantibody

- The beneficiary must have preserved beta-cell function shown by Peak C-peptide level ≥ 0.2 pmol/mL on Mixed-Meal Tolerance Test (MMTT) or another stimulated test if MMTT is not available.
- Treatment must be initiated as soon as possible following Stage 3 T1D diagnosis but no later than 8 weeks from diagnosis
- Approval durations were modified to include approval for 3 months and added stage 2 T1D. Stage 3 T1D approval is for 12 dose and may be renewed one time on a case-by-case basis for total of 24 infusion days
- Recommended dosage and administration were modified to include new indications for stage 3 T1D
- Renewal/Reauthorization were also modified to include stage 2 T1D and stage 3 T1D. Stage 3 T1D included disease response with treatment, as defined by evidence of preserved beta-cell function shown by a current Peak C-peptide level ≥ 0.2 pmol/mL on Mixed-Meal Tolerance Test (MMTT) or another stimulated test if MMTT is not available, absence of unacceptable toxicity from the drug (current labs including complete blood count and liver enzyme tests must be submitted), and the beneficiary-specific treatment plan and infusion schedule must be provided.

DISCUSSION:

Dr. Pearson clarified with Dr. Golden that the vote would be made for all changes made to each updated monograph to be voted on at one time. Dr. Golden affirmed that he would agree that unless people want to extract an item, I would move the entire group of materials presented as a consent calendar, subject to any extraction. Dr. Douglass clarified that she did not vote specifically for the GILEAD product.

ACTION:

Motion to approve the changes as presented for Ocrevus, Tecentriq, Imfinzi, Trodelvy, and Tziel was made by Dr. Golden; second by Dr. Smith. All voting members present voted for approval (excluding Dr. Douglass for the conflict of interest with GILEAD). Motion passed.

New Monographs

1. YARTEMLEA (narsoplimab-wuug) 370 mg/2ml injection

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)
- Dosing information consistent with package insert
- Warning/Contraindications include serious and life-threatening infections that have occurred in patients being treated
- Clinical Trial information included the TA-TMA Study
- YARTEMLEA draft approval criteria

DISCUSSION:

No comment.

ACTION:

Motion to approve the new monograph as presented was made by Dr. Crawley; second by Dr. Smith. All voting members present voted for approval. Motion passed.

2. KISUNLA (donanemab-azbt) 350 mg/20mL injection

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of Alzheimer's disease and should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials
- Dosing information consistent with package insert
- Warning/Contraindications include hypersensitivity, amyloid-related imaging abnormalities (ARIA) (Black Box Warning), and infusion-related reactions.
- Clinical Trial information included Trailblazer-ALZ 2 and Trailblazer-ALZ 6 studies
- KINSULA draft approval criteria

DISCUSSION:

Dr. Smith suggested to keep things consistent by adding board certified. Dr. Golden clarified that the language used was fellowship trained. Dr. Pearson confirmed adding fellowship trained. Dr. Golden stated yes.

ACTION:

Motion to approve the new monograph as amended was made by Dr. Golden; second by Dr. Max. All voting members present voted for approval. Motion passed.

3. ZIIHERA (zanidatamab-hrii) injection

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), and gastroesophageal adenocarcinoma
- Dosing information consistent with package insert
- Warning/Contraindications include embryo-fetal toxicity (Black Box Warning), can cause decrease in left ventricular ejection fraction, can cause infusion-related reactions which prompt pre-medication use, and severe diarrhea
- Clinical Trial information included Herizon-BTC-01 and Herizon-GEA-01 studies
- ZIIHERA draft approval criteria

DISCUSSION:

Dr. Smith had a question about whether there was a definition explaining the meaning of adequate in the clinical criteria on the left ventricular ejection fraction being adequate in the renewal. Dr. Pearson stated that it did not give the actual number. Dr. Smith stated that adequate could be interpreted in many ways and using a specific number would be nice to include. Dr. Pearson asked Dr. Owens if she had a specific number on the package insert, and Dr. Owens stated she would have to look again and agreed with Dr. Smith that adequate could be interpreted in many ways. Dr. Pearson stated she would move forward pending the definition could be found and the LVEF could be approved as amended.

Drug Rep added comments in the chat

Hello, this is Michael Faithe, from Jazz Pharmaceuticals. For the question on what was the baseline EF for Ziihera for 1L GEA indication, the inclusion criteria from the study was as follows: Left ventricular ejection fraction (LVEF) $\geq 50\%$ as determined by either echocardiogram or multiple gated acquisition scan (MUGA). There are specific dose reduction criteria in the label based on changes in EF. Please let me know if you have any additional questions.

Emails with voting subcommittee: the members decided to require initial LVEF of $\geq 50\%$ and on renewal

- If absolute LVEF decrease is $\geq 16\%$ from baseline, or LVEF $< 50\%$ with an absolute decrease $\geq 10\%$ below baseline, withhold treatment for at least 4 weeks and recheck LVEF within 4 weeks
 - Resume treatment if LVEF recovers to normal limits and the absolute decrease is $\leq 15\%$ from baseline.
 - Permanently discontinue treatment if LVEF does not recover to within 15% of baseline

ACTION:

Motion to approve the new monograph as amended was made by Dr. Smith; second by Dr. Golden. All voting members present voted for approval. Motion passed.

4. TEVIMBRA (tislelizumab-jsgr) injection

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of Esophageal Cancer and Gastric Cancer
- Dosing information consistent with package insert
- Warnings include severe and fatal immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity
- Clinical trial information included the Rational-306, Rational-305, and Rational-302 studies
- TEVIMBRA draft approval criteria

DISCUSSION:

No comment.

ACTION:

Motion to approve the new monograph as presented was made by Dr. Smith; second by Dr. Golden. All voting members present voted for approval. Motion passed.

ANNOUNCEMENT:

Dr. Pearson announced that we had reached 1:00pm and verified who on the board was able to stay past time for the monographs left to be presented. Dr. Golden, Dr. Smith, and Dr. Max were able to stay on, but Dr. Crawley and Dr. Douglass had to leave the meeting. The meeting retained a quorum.

5. YEZTUGO (lenacapavir) tablet/injection

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating
- Dosing information consistent with the package insert
- Warning/Contraindications include that it is contraindicated in unknown or positive HIV-1 status (black box warning), patients need a comprehensive management plan to reduce the risk of HIV-1 infection, and there is risk of resistance
- Clinical trial included the Purpose 1 and Purpose 2 studies
- YEZTUGO draft approval criteria

DISCUSSION:

No comment.

ACTION:

Motion to approve the new monograph as presented was made by Dr. Max; second by Dr. Golden. All voting members present voted for approval. Motion passed.

6. ZUSDURI (mitomycin) kit

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).
- Dosing information consistent with package insert
- Warning/Contraindications include that it is contraindicated in perforation of the bladder, in mitomycin hypersensitivity and embryo-fetal toxicity.
- Clinical trial included the Envision study
- ZUSDURI draft approval criteria

DISCUSSION:

No comment.

ACTION:

Motion to approve the new monograph as presented was made by Dr. Golden; second by Dr. Max. All voting members present voted for approval. Motion passed.

7. ADSTILADRIN (nadofaragene firadenovec-vncg) suspension

Dr. Owens provided the following drug information and recommended monograph language for review.

- Indication for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
- Dosing information consistent with package insert
- Warning/Contraindications include that it is contraindicated in patients with prior hypersensitivity reactions to interferon alfa or to any component of the product. There is a risk of muscle invasive or metastatic bladder cancer with delayed cystectomy and of disseminated adenovirus infection.
- Clinical trial included the CS-003 study
- ADSTILADRIN draft approval criteria

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		DISCUSSION: No comment. ACTION: Motion to approve the new monograph as presented was made by Dr. Smith; second by Dr. Golden. All voting members present voted for approval. Motion passed.
Board comments		Dr. Pearson shared the future meeting dates.
Adjourn		Meeting was adjourned at 1:07 pm.

DRAFT