Managed Healthcare EXECUTIVE®

The C-Suite Advisor

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SPECIAL ISSUE

2024 EMERGING LEADERS IN HEALTHCARE

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EYLEA® HD
(aflibercept) Injection 8 mg

Lasting Control, Fewer Injections[1,2]

Patients with Wet AMD receiving EYLEA HD achieved robust vision gains with fewer injections than EYLEA® (aflibercept) Injection at week 48[1,2]

PULSAR primary endpoint: Mean change in BCVA (ETDRS letters) from baseline at week 48 was 6.2 letters gained for EYLEA HD Q16W, 6.7 letters for EYLEA HD Q12W, and 7.6 letters for EYLEA 2 mg Q8W.* LS mean differences were noninferior to EYLEA 2 mg using a margin of 4 letters: -1.1 letters (95% CI, -3.0 to 0.7) for EYLEA HD Q16W and -1.0 letters (95% CI, -2.9 to 0.9) for EYLEA HD Q12W. Patients received 3 initial monthly doses.[1]

- Fewer mean number of injections: 5.2 for EYLEA HD Q16W and 6.1 for EYLEA HD Q12W vs 6.9 for EYLEA 2 mg Q8W[1†]

*FAS at baseline: EYLEA HD Q16W (n=338), EYLEA HD Q12W (n=335), EYLEA 2 mg Q8W (n=336). FAS; observed values (censoring data post ICE) at week 48: EYLEA HD Q16W (n=289), EYLEA HD Q12W (n=299), EYLEA 2 mg Q8W (n=285).[1,2]

†Patients who completed week 48: EYLEA HD Q16W (n=312), EYLEA HD Q12W (n=316), EYLEA 2 mg Q8W (n=309).[1]

Extended dosing

In PULSAR, 83% of patients with Wet AMD in the combined EYLEA HD group **maintained ≥Q12W dosing** through week 48[2‡]

PULSAR study design: Multicenter, randomized, double-masked study in which treatment-naïve patients with Wet AMD (N=1009; age range: 50-96 years, with a mean of 74.5 years) were randomized to receive EYLEA HD Q12W (n=335),§ EYLEA HD Q16W (n=338),§ or EYLEA 2 mg Q8W (n=336),§ following 3 initial monthly doses for each treatment group. In the EYLEA HD groups, patients could be treated as frequently as every 8 weeks based on protocol-defined visual and anatomic criteria starting at week 16.[1,2]

INDICATIONS

EYLEA® HD (aflibercept) Injection 8 mg is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

EYLEA® (aflibercept) Injection 2 mg is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

IMPORTANT SAFETY INFORMATION FOR EYLEA HD AND EYLEA

CONTRAINDICATIONS

- EYLEA HD and EYLEA are contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA HD or EYLEA.

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with aflibercept, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering EYLEA HD or EYLEA. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA HD and EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA HD and EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).
    - EYLEA HD: The incidence of reported thromboembolic events in the wet AMD study (PULSAR) from baseline through week 48 was 0.4% (3 out of 673) in the combined group of patients treated with EYLEA HD compared with 1.5% (5 out of 336) in patients treated with EYLEA 2 mg. The incidence in the DME study (PHOTON) from baseline to week 48 was 3.1% (15 out of 491) in the combined group of patients treated with EYLEA HD compared with 3.6% (6 out of 167) in patients treated with EYLEA 2 mg.

EYLEA HD Is the FIRST and ONLY Anti-VEGF Treatment Approved in Wet AMD for Immediate Dosing at Q8W (+/- 7 days) and up to Q16W Intervals Following 3 Initial Monthly Doses[1]

Vision:

Noninferior vision gains achieved at week 48 with **fewer injections** vs EYLEA 2 mg[1,2‡‖]

Safety:

Safety of EYLEA HD was **consistent with the established profile** of EYLEA 2 mg[1,3]

Pricing:

EYLEA HD has comparable pricing with EYLEA 2 mg Q8W following 3 initial monthly doses for a full year of treatment[1,3-5]

‡Following 3 initial monthly injections. Proportion of patients maintaining their randomized dosing intervals through week 48: EYLEA HD Q16W (n=312) 77% (11% shortened to Q12W and 13% shortened to Q8W) and EYLEA HD Q12W (n=316) 79% (21% shortened to Q8W). Patients completing week 48. Values do not total 100% due to rounding.[2]

§FAS at baseline.

‖Vision gains were measured by mean change in BCVA (ETDRS letters) from baseline at week 48. FAS; observed values (censoring data post ICE) at week 48: EYLEA HD Q12W (n=299), EYLEA HD Q16W (n=289), EYLEA 2 mg Q8W (n=285).

AMD = age-related macular degeneration; BCVA = best corrected visual acuity; ETDRS = Early Treatment Diabetic Retinopathy Study; FAS = full analysis set; ICE = intercurrent events; LS = least squares; Q8W = every 8 weeks; Q12W = every 12 weeks; ≥Q12W = more than or equal to every 12 weeks; Q16W = every 16 weeks; VEGF = vascular endothelial growth factor.

IMPORTANT SAFETY INFORMATION FOR EYLEA HD AND EYLEA

WARNINGS AND PRECAUTIONS (cont'd)

- EYLEA: The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

- EYLEA HD:
  - The most common adverse reactions (≥3%) reported in patients receiving EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage.
- EYLEA:
  - Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
  - The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA HD or EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Please see Brief Summary of Prescribing Information for EYLEA HD and EYLEA on the following page.

References: 1. EYLEA HD full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. December 2023. **2.** Lanzetta P, Korobelnik J-F, Heier JS, et al; PULSAR Investigators. Intravitreal aflibercept 8 mg in neovascular age-related macular degeneration (PULSAR): 48-week results from a randomised, double-masked, non-inferiority, phase 3 trial. *Lancet*. 2024;403(10432):1141-1152. **3.** EYLEA full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. December 2023. **4.** Data on file. Regeneron Pharmaceuticals, Inc. **5.** Red Book Online. IBM Micromedex. Accessed March 15, 2024. www.micromedexsolutions.com

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Discover more about EYLEA HD

EYLEA® HD (aflibercept) Injection 8 mg, for intravitreal use AND EYLEA® (aflibercept) Injection 2 mg, for intravitreal use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

4. CONTRAINDICATIONS

4.1 Ocular or Periocular Infections EYLEA HD and EYLEA are contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation EYLEA HD and EYLEA are contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity EYLEA HD and EYLEA are contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA HD or EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis, Retinal Detachments, and Retinal Vasculitis with or without Occlusion Intravitreal injections including those with aflibercept have been associated with endophthalmitis and retinal detachments *[see Adverse Reactions (6.1)]* and, more rarely, retinal vasculitis with or without occlusion *[see Adverse Reactions (6.2)]*. Proper aseptic injection technique must always be used when administering EYLEA HD or EYLEA. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment or retinal vasculitis without delay and should be managed appropriately [*see Dosage and Administration (2.6 EYLEA HD, 2.4 EYLEA) in the full Prescribing Information and Patient Counseling Information (17)*].

5.2 Increase in Intraocular Pressure Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA HD and EYLEA [*see Adverse Reactions (6.1)*]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.6 EYLEA HD, 2.4 EYLEA) in the full Prescribing Information*].

5.3 EYLEA HD, 5.4 EYLEA Thromboembolic Events There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA HD and EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

- **EYLEA HD:** The incidence of reported thromboembolic events in the wet AMD study (PULSAR) from baseline through week 48 was 0.4% (3 out of 673) in the combined group of patients treated with EYLEA HD compared with 1.5% (5 out of 336) in patients treated with EYLEA 2 mg. The incidence of reported thromboembolic events in the DME study (PHOTON) from baseline to week 48 was 3.1% (15 out of 491) in the combined group of patients treated with EYLEA HD compared with 3.6% (6 out of 167) in patients treated with EYLEA 2 mg.
- **EYLEA:** The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [*see Contraindications (4.3)*]
- Endophthalmitis, retinal detachments and retinal vasculitis with or without occlusion [*see Warnings and Precautions (5.1)*]
- Increase in intraocular pressure [*see Warnings and Precautions (5.2)*]
- Thromboembolic events [*see Warnings and Precautions (5.3 for EYLEA HD, 5.4 for EYLEA)*]

6.1 Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice.

- **EYLEA HD:** A total of 1164 patients were treated with EYLEA HD and 503 patients were treated with EYLEA 2 mg in two clinical studies. The most common adverse reactions reported in ≥3% of patients treated with EYLEA HD were cataract, conjunctival hemorrhage, intraocular pressure increased, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage.
- **EYLEA:** A total of 2980 adult patients treated with EYLEA constituted the safety population in eight phase 3 studies. Among those, 2379 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Neovascular (Wet) Age-Related Macular Degeneration (Wet AMD)

EYLEA HD: The data described below reflect exposure to EYLEA HD or EYLEA 2 mg in 1009 patients with Wet AMD, in 1 double-masked, controlled clinical study (PULSAR) for 48 weeks [*see Clinical Studies (14.1) in the full Prescribing Information*].

EYLEA: The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, controlled clinical studies (VIEW 1 and VIEW 2) for 24 months (with active control in year 1) [*see Clinical Studies (14.1) in the full Prescribing Information*].

Safety data observed in the EYLEA group in a 52-week, double-masked, phase 2 study were consistent with these results.

Table 1: Most Common Adverse Reactions (≥1%) in Wet AMD Studies

	PULSAR ARs (≥1%) in at least one group			VIEW 1 and VIEW 2 Baseline to Week 52		VIEW 1 and VIEW 2 Baseline to Week 96	
Adverse Reactions	EYLEA HD q12 (n=335)	EYLEA HD q16 (n=338)	EYLEA 2q8 (n=336)	EYLEA (n=1824)	Active Control (ranibizumab) (n=595)	EYLEA (n=1824)	Control (ranibizumab) (n=595)
Conjunctival hemorrhage[a]	3%	2%	1%	25%	28%	27%	30%
Eye pain	-	-	-	9%	9%	10%	10%
Ocular discomfort/eye pain/eye irritation[a]	3%	3%	2%	-	-	-	-
Cataract[a]	4%	4%	4%	7%	7%	13%	10%
Vitreous detachment[a]	2%	3%	2%	6%	6%	8%	8%
Vitreous floaters[a]	1%	4%	3%	6%	7%	8%	10%
Intraocular pressure increased[a]	4%	4%	2%	5%	7%	7%	11%
Ocular hyperemia[a]	-	-	-	4%	8%	5%	10%
Corneal epithelium defect[a]	2%	2%	3%	4%	5%	5%	6%
Retinal pigment epithelial detachment[a]	1%	1%	2%	3%	3%	5%	5%
Injection site pain	-	-	-	3%	3%	3%	4%
Foreign body sensation in eyes[a]	1%	1%	2%	3%	4%	4%	4%
Lacrimation increased	-	-	-	3%	1%	4%	2%
Vision blurred[a]	4%	6%	7%	2%	2%	4%	3%
Intraocular inflammation[a]	1%	1%	1%	2%	3%	3%	4%
Retinal pigment epithelial tear	-	-	-	2%	1%	2%	2%
Retinal pigment epithelial tear/ epitheliopathy[a]	2%	1%	2%	-	-	-	-
Injection site hemorrhage	-	-	-	1%	2%	2%	2%
Eyelid edema	-	-	-	1%	2%	2%	3%
Corneal edema	-	-	-	1%	1%	1%	1%
Retinal detachment[a]	1%	<1%	0%	<1%	<1%	1%	1%
Retinal hemorrhage	3%	3%	4%	-	-	-	-
Vitreous hemorrhage	<1%	1%	1%	-	-	-	-

Reported terms differ between the PULSAR and VIEW 1 and VIEW 2 studies, as indicated by dashes in the table.

[a]Represents grouping of related terms in PULSAR

Adverse drug reactions (ADRs) reported in <1% of participants treated with EYLEA HD were ocular hyperemia (includes adverse events of conjunctival hyperemia, conjunctival irritation, ocular hyperemia), lacrimation increased, eyelid edema, hypersensitivity (includes adverse events of rash, urticaria, pruritus), retinal tear, and injection site hemorrhage.

Less common serious adverse reactions reported in <1% of the patients treated with EYLEA in VIEW 1 and VIEW 2 were hypersensitivity, retinal tear, and endophthalmitis.

6.2 Postmarketing Experience The following adverse reactions have been identified during postapproval use of aflibercept. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Eye disorders: retinal vasculitis and occlusive retinal vasculitis related to intravitreal injection with aflibercept (reported at a rate of 0.6 and 0.2 per 1 million injections, respectively, based on postmarketing experience from November 2011 until November 2023).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Risk Summary Adequate and well-controlled studies with EYLEA HD and EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposure (based on AUC for free aflibercept) was approximately 0.9-fold of the population pharmacokinetic estimated exposure in humans after an intravitreal dose of 8 mg for EYLEA HD and approximately 6 times higher than AUC values observed in humans after a single intravitreal treatment at the recommended clinical dose of 2 mg for EYLEA [*see Data*].

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA HD or EYLEA can cause fetal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [*see Clinical Pharmacology (12.1) in the full Prescribing Information*], treatment with EYLEA HD or EYLEA may pose a risk to human embryofetal development. EYLEA HD and EYLEA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data *Animal Data* In two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesis at subcutaneous doses ≥0.1 mg per kg.

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level (NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free aflibercept was approximately 0.9-fold of the population pharmacokinetic estimated systemic exposure (AUC) in humans after an intravitreal dose of 8 mg for EYLEA HD and approximately 6 times higher than systemic exposure (AUC) observed in adult patients after a single intravitreal dose of 2 mg for EYLEA.

8.2 Lactation Risk Summary There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists, EYLEA HD and EYLEA are not recommended during breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA HD or EYLEA and any potential adverse effects on the breastfed child from EYLEA HD or EYLEA.

8.3 Females and Males of Reproductive Potential Contraception Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 4 and 3 months after the last intravitreal injection of EYLEA HD or EYLEA, respectively.

Infertility There are no data regarding the effects of EYLEA HD or EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose 91 times higher (based on AUC of free aflibercept) than the corresponding systemic level estimated based on population pharmacokinetic analysis in humans following an intravitreal dose of 8 mg for EYLEA HD and at a dose approximately 1500 times higher than the systemic level observed in adult patients with an intravitreal dose of 2 mg for EYLEA. A No Observed Adverse Effect Level (NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [*see Nonclinical Toxicology (13.1) in the full Prescribing Information*].

8.4 Pediatric Use The safety and effectiveness of EYLEA HD in pediatric patients have not been established.

The safety and effectiveness of EYLEA have been demonstrated in two clinical studies of pre-term infants with Retinopathy of Prematurity. These two studies randomized pre-term infants between initial treatment with EYLEA or laser. Efficacy of each treatment is supported by the demonstration of a clinical course which was better than would have been expected without treatment [*see Dosage and Administration (2.9), Adverse Reactions (6.1), Clinical Pharmacology (12.3) and Clinical Studies (14.6) in the full Prescribing Information for EYLEA*].

8.5 Geriatric Use In PULSAR, approximately 90% (604/673) of the patients in the HDq12 and HDq16 groups were 65 years of age or older and approximately 51% (343/673) were 75 years of age or older.

In PHOTON, approximately 44% (214/491) of the patients in the HDq12 and HDq16 groups were 65 years of age or older and approximately 10% (50/491) were 75 years of age or older.

In the clinical studies for EYLEA 2 mg, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

10 OVERDOSAGE Overdosing with increased injection volume may increase intraocular pressure. Therefore, in case of overdosage, intraocular pressure should be monitored and if deemed necessary by the treating physician, adequate treatment should be initiated.

17 PATIENT COUNSELING INFORMATION In the days following EYLEA HD or EYLEA administration, patients are at risk of developing endophthalmitis, retinal detachment or retinal vasculitis with or without occlusion. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients and/or caregivers to seek immediate care from an ophthalmologist [*see Warning and Precautions (5.1)*]. Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA HD or EYLEA and the associated eye examinations [*see Adverse Reactions (6)*]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

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Up to the challenge

In an ideal, imagined world, you would not be meeting the 14 emerging leaders in healthcare we selected in these pages but in person. You could talk to Courtney Bragg, MBA, about cofounding Fabric Health and trust building and teachable moments in healthcare. Or chat with Anoop Raman, M.D., MBA, of AbsoluteCare about his work with Paul Farmer, M.D., and Partners In Health in Rwanda. One of Nick Stepro's first customers was Jim O'Connell, M.D., M.Theol., the founding physician and president of Boston Health Care for the Homeless Program and the subject of Tracy Kidder's 2023 bestseller, "Rough Sleepers." We would like to talk to Jamie Bullus, M.P.H., of Optum Rx, about Otis Brawley, M.D., and his book "How We Do Harm: A Doctor Breaks Ranks About Being Sick in America." Bullus picked Brawley's book in response to our question about a book or article everyone working in healthcare should read. Brawley was on the *Managed Healthcare Executive* (*MHE*) editorial advisory board for several years, so it was good to see that his landmark book is still read and recommended.

We also will not have a chance to meet these emerging leaders in person. However, the editors have had a chance to interview them all on Zoom to ask them three of the questions for which we asked written answers. We will post short video clips from those interviews on the *MHE* website this month. Please check them out. As many have learned after the COVID-19 pandemic eased up, video chats cannot replace encountering people in person. But we have all discovered the power of those platforms and how they can bring someone to life.

Once you get to know these emerging leaders in these pages and through the video clips, we hope you will experience what we have this and every year that we put the emerging leaders list together: a wave of optimism and excitement about the future of U.S. healthcare. The challenges of managing costs, streamlining delivery and alleviating inequity are steep. But this group inspires renewed confidence that we can gain a foothold on them — that there are opportunities for innovation and insightful intervention that can make a lasting difference in healthcare and people's health and well-being.

We hope the careers of these emerging leaders progress and that they get a chance to assume larger leadership roles. If we are lucky, we will get an opportunity to meet them in person. ■

Mike Hennessy Jr.
President and CEO
of MJH Life Sciences

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Editorial Advisory Board

Mission *Managed Healthcare Executive*® provides healthcare executives at health plans and provider organizations with analysis, insights and strategies to pursue value-driven solutions.

Two more TROP2-seeking ADCs in late-stage development

If approved, they would join Trodelvy as a treatment for triple-negative breast cancer.

By **ROSANNA SUTHERBY, PHARM.D.**

Triple-negative breast cancer accounts for about 15% of breast cancers and is considered the most aggressive type, with a five-year survival rate of approximately 30%. The four-year survival rate for patients with metastatic cases is about 11%. Current standard treatment consists of chemotherapy alone or combined with immunotherapy, followed by tumor removal for nonmetastatic stages.

Antibody-drug conjugates (ADCs) have been making a mark in oncology because they target cancer cells and deliver tumor-killing payloads with fewer side effects than traditional chemotherapy. They consist of an antibody that homes in on a specific biomarker on tumor cells, a chemotherapy agent that is released once the antibody attaches to the cancer cell, and a linker that connects the two.

Trophoblast cell surface antigen 2 (TROP2) is a protein rarely found in healthy tissue but widely expressed in triple-negative breast cancer and other solid tumors. It is associated with increased tumor progression and a poor prognosis for people with breast cancer. The FDA approved Trodelvy (sacituzumab govitecan), a TROP2-directed ADC, as a treatment for triple-negative breast cancer in 2021. Two other TROP2-directed ADCs are late-stage trials.

Datopotamab deruxtecan

AstraZeneca has partnered with Daiichi Sankyo, a Japanese company, to develop datopotamab deruxtecan, an investigational TROP2-targeted ADC. Datopotamab deruxtecan consists of a humanized anti-TROP2 immunoglobulin G1 monoclonal antibody linked to a highly potent exatecan-derived topoisomerase I inhibitor. A serum-stable cleavable linker is designed to reduce systemic exposure of the payload, which can lead to off-target side effects.

Antibody-drug conjugates consist of an antibody that homes in on cancer cells, a chemotherapy agent and a linker that connects the two.

Researchers are evaluating datopotamab deruxtecan as a treatment for triple-negative breast cancer in two phase 3 trials. The TROPION-Breast04 trial is evaluating first-line datopotamab deruxtecan plus the immune checkpoint inhibitor Imfinzi (durvalumab) followed by Imfinzi as adjuvant therapy with or without chemotherapy in participants with early-stage triple-negative breast cancer or HR or HER2 low or negative breast cancer. The primary end points are pathological complete response and event-free survival.

The TROPION-Breast05 study is evaluating the use of datopotamab deruxtecan alone and combined with Imfinzi in adults with locally advanced or metastatic triple-negative breast cancer with PD-L1-expressing tumors. The primary end point for this trial is progression-free survival. The FDA recently accepted an application for the use of datopotamab deruxtecan in HR-positive/HER2-negative metastatic breast cancer.

Sacituzumab tirumotecan

Merck is collaborating with Sichuan Kelun-Biotech, a Chinese company, to develop sacituzumab tirumotecan, an investigational ADC consisting of a TROP2-targeting antibody linked to a belotecan-derived topoisomerase I inhibitor payload. The conjugate has a novel linker that allows for pH-based cleavage of the ADC outside the cell and enzyme-based cleavage inside.

Data from the phase 3 OptiTROP-Breast01 study were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and published in abstract form in the May 2024 issue of the *Journal of Clinical Oncology*. Sacituzumab tirumotecan demonstrated significant progression-free survival and overall survival compared with physician's choice of chemotherapy in participants with locally recurrent or metastatic triple-negative breast cancer.

Rosanna Sutherby, Pharm.D., *is a medical writer and community pharmacist in High Point, North Carolina.*

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Emerging Leaders

IN HEALTHCARE

WELCOME TO OUR 2024 Emerging Leaders in Healthcare feature! We are thrilled to have 14 outstanding people on this year's list. We tightened up the criteria this year to put a spotlight on individuals early in their careers, emphasizing the "emerging" in emerging leaders. Watching the arc of these careers in the years ahead will be exciting. Check out our website for video clips of the winners answering three of the questions we posed in our questionnaire. Healthcare is beset with challenges. These young leaders give us confidence that those challenges can be met and that the future of U.S. healthcare is in the best of hands.

—The editors

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Katie Acker, M.P.H.

Health equity program director, Fallon Health, a not-for-profit health plan and provider of care headquartered in Worcester, Massachusetts

I grew up in a military family and lived in eight different places, including in the U.S. and Europe, by the time I graduated from high school. Experiencing new environments, meeting new people, learning and adapting to different lifestyles and cultures every few years has no doubt shaped who I am today.

I earned my B.S. from Marymount University in Arlington, Virginia, and an internship at the Pan American Health Organization quickly changed my career interests from medicine to public health. I later earned my M.P.H. from the University of Washington. Serving as a Peace Corps volunteer was a valuable experience and led me to focus my career on gaining knowledge and experience addressing upstream causes of poor health and inequities.

I came to Fallon Health in 2018, eager to learn more about the payer role in healthcare and to find ways to leverage my unique experiences to positively impact the organization's members and communities it serves. I quickly saw how dedicated the organization is to addressing barriers to healthcare access and how much further upstream the payer is in impacting health outcomes of the very communities I had been working with.

CAREER TURNING POINT: I had a professor in grad school start their lecture by saying, "Congratulations on pursuing a degree where the goal of your entire career will be to put yourself out of a career." The statement has stuck with me for over 10 years. And I have found myself asking the question, "Is the goal of this job to put myself out of work?" with each opportunity I pursue. With equity work, I don't just want to improve the health of disadvantaged populations; I want there to be no disadvantaged populations — a much greater motivation to continue to push the boundaries.

TOP TWO PRIORITIES: One of my priorities as a leader at Fallon Health is to continue to build and strengthen the organization's confidence and capacity to acknowledge, identify and address inequities by embedding equity into our routine responsibilities. Additionally, over the past two years, I have been leading our organization's efforts to collect, store and report on more complete, accurate and comprehensive data of both our membership and our provider network. Nearly everything we do to understand inequities and make positive change is dependent on data.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: I would love to change the accessibility and cost of education for healthcare-related fields. Although there are many challenges in the healthcare industry, two that stand out when speaking to our members and communities are that there are not enough doctors (medical staff in general) and there is a severe lack of diversity in healthcare. We would not solve these problems with free education and training, but that would make a substantial impact on both.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: With young children, my book recommendations are two of my daughter's favorites: "No! My First Book of Protest" by Julie Merberg and "Antiracist Baby" by Ibram X. Kendi. I also recommend the podcast "More Perfect" by WNYC Studios. It offers an invaluable look at the power of laws and policies and how easily they can build or break trust among communities.

WORK-LIFE BALANCE: Having two young children provides a welcome chaos while giving me perspective and purpose. With my family's support, I am able to passionately pursue my work with their future in the forefront of my mind. And at the end of the day, they bring me great comfort as I "turn off" my professional role and transition back to "parent and spouse." Having an amazing wife who works in the craft beer industry doesn't hurt, either.

DREAM DINNER COMPANION: One of my favorite quotes comes from astrophysicist Neil deGrasse Tyson, who said, "The good thing about science is that it's true whether or not you believe in it." The quote is also permanently a part of me as a favorite and probably my most publicly admired tattoo. I have been to a number of talks and shows where I was listening to him from the nosebleed seats. Having a meal with him would have me giddy. I admire the way he can take complicated topics and make them exciting, engaging and logical to any audience.

Eden Avraham-Katz, J.D.

General counsel, 1upHealth, Inc., a healthcare data interoperability company in Boston

I spent the majority of my childhood and young adult years in North Carolina, which includes attending college at Elon University. After graduating from Elon in 2012, I attended Northeastern University School of Law in Boston. I knew I wanted to be an attorney since the age of 7, but it was during my second year at Northeastern, through my participation in the Intellectual Property Law Clinic, where I developed my love of working with start-up companies. After graduating, I took an in-house role at InterSystems Corporation in Cambridge, Massachusetts, where I got my first taste of the healthcare industry. My knowledge and experience in the healthcare space developed during my next job as corporate counsel at PatientPing, Inc., now Bamboo Health, where I developed both a deeper understanding of privacy law and an appreciation for the healthtech industry, as well as developed the skill sets necessary to be the general counsel of 1upHealth.

CAREER TURNING POINT: I think a true turning point in my career was was when I became a consumer of our healthcare system through my mother's battle with pancreatic cancer. Despite how broken our system is and the burden that places on families, patients and caregivers, I came across so many amazing doctors and nurses who truly wanted to give my mother the best care they could. We hear so many jarring statistics in this industry, and until those numbers get faces added to them, they are quite easy to disregard. However, despite all statistics, it was the same incredibly broken healthcare system that gave my mother seven years of life she would not have otherwise had. It was that very realization that made all the frustration at this system, both personally and professionally, worth every second.

TOP TWO PRIORITIES: As an attorney in the healthcare space, my first priority is always patient privacy. How do we ensure that an individual's right to privacy is protected and that their data (are) secure? My second priority, which sometimes (and by sometimes, I mean almost always) feels in conflict with the first, is how can we improve the healthcare industry today by supporting the ability to exchange relevant data in a safe and secure manner to all organizations and entities such information to provide better, more cost-effective care?

CHANGE ONE THING ABOUT U.S. HEALTHCARE: This is a really hard question to answer because the system is inherently so broken, but the first thing I would work to change is helping to shift the perspective held so strongly today around data sharing. Although we have seen an uptick in both state and federal regulations in support of interoperability, there is still so much hesitation to share data. Most of the concern is couched under the guise of protecting patient privacy, but the reality is that organizations do not really want to share certain data because it both negatively impacts some of their financial incentives and the relatively high administrative cost.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "America's Bitter Pill: Money, Politics, Backroom Deals, and the Fight to Fix Our Broken Healthcare System" by Steven Brill.

WORK-LIFE BALANCE: I think is really important to set clear boundaries around working hours and, barring emergency situations or time-sensitive matters, really holding myself to those boundaries. Earlier in my career, when I used to receive emails or Slacks after hours or on the weekend, I felt immediate pressure to respond, and as a result, I missed out on moments with friends and family. After a very challenging 2023, I feel like I have really had a shift in perspective, and while it sounds cliché, it is just so true that at work, we are all replaceable, but at home, we are really not.

DREAM DINNER COMPANION: Last year was a hard year. I lost my mother to pancreatic cancer in late September, so she would be the obvious choice for me here. There have been so many times over the last few months where I wish I could call her, and while I would love to be able to share all the updates in my life, what I would want the most is to get to see her again and spend time with her while she was not suffering or in pain.

Nisha Bhide, Pharm.D.

Director, formulary operations, Capital Rx, a pharmacy benefits manager and healthcare technology company

I grew up in East Brunswick, New Jersey, and went to Rutgers University for pharmacy school, where I ,received my doctor of pharmacy degree. I learned the value of hard work, dedication and grit from my entrepreneurial parents, who motivated me to continue training through residency and fellowship. I was the first postgraduate year (PGY) 2 corporate health-system pharmacy administration resident and the first executive pharmacy leadership and supply chain management fellow at Ascension/The Resource Group. The exposure and learning from those two years set me up for every opportunity I have had since. As director of formulary operations and the PGY1 managed care residency program director, I built the formulary operations team from the ground up to serve all lines of business, including commercial, health insurance marketplaces, Medicaid and Medicare, and supported the company's state-of-the-art claim adjudication platform. I serve in multiple local, regional and national committees and positions, including the US Pharmacopeia healthcare safety and quality expert committee.

CAREER TURNING POINT: Most of my career has been steadily built upon experiences and opportunities. I found confidence in myself when I created my first pharmacist role as Ascension senior manager of pharmacy deployment following residency and fellowship training. I was able to take all the learning and experiences from pharmacy school and postdoc training and apply it in a professional setting. From leading mergers and hospital acquisitions to operationalizing Accreditation Council for Pharmacy Education-accredited continuing education to supporting over 120 health system clinical and operational initiatives, I came into my own as a healthcare and pharmacy leader and had the support of my mentors and leaders.

TOP TWO PRIORITIES: As a leader in healthcare, I continue to prioritize staying on top of the always-changing healthcare landscape as well as pipeline medication approvals and changes. Additionally, I prioritize developing future pharmacy leaders by leading Capital Rx's advanced pharmacy practice experiences program with multiple schools of pharmacy and directing our PGY1 Managed Care Residency Program.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Much of healthcare is siloed and segmented, which can be confusing to both patients and healthcare teams. If I could change one thing, it would be integration of all health information, through perhaps unified healthcare claims processing, in one place for it to be available to those taking care of patients.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: I recommend that everyone read the various articles KFF Health News publishes. KFF is an independent source for health policy research, polling and journalism, and it does a great job of explaining impactful and complicated health policy issues in a clear and understandable way.

WORK-LIFE BALANCE: It is always tough to strike the right work-life balance, especially early in one's career, when you do not want to give up an exciting learning or growth opportunity. I strive every day to utilize my personal and work calendars to prioritize items and due dates, delegate when possible and disconnect completely to be fully present at home with family when away from the computer.

DREAM DINNER COMPANION: I wish I could have dinner with myself when I was around 23 years old to help that version of myself see the many possibilities the future holds and how to be excited about them. Otherwise, I would have dinner with Warren Buffett because he explains things in graspable ways that everyone can understand, he thinks in a methodical way and has amassed success.

Courtney Bragg, MBA

Co-founder and CEO at Fabric Health, a public benefit corporation that conducts outreach about health benefits at laundromats

I grew up in South Florida in a majority-minority high school and was fascinated by the divisions and opportunities that dominated my high school, Cypress Bay High School, in Weston, Florida, one of the largest in the U.S. My favorite teacher, Dianne Farbiarz, opened the world and, therein, my complacency during English, both in the level of reading and writing rigor she expected but also because she pushed me to give back to my community. I planned to study business at Washington University in St. Louis but transferred to urban studies and education my freshman year after having student-taught, thanks to Ms. Farbiarz.

Now my work has come full circle. After earning my MBA at Dartmouth's Tuck School of Business, I co-founded Fabric Health, which exists to improve the health and well-being of families by partnering with health plans to provide trusted, last-mile engagement to their hardest-to-reach members.

CAREER TURNING POINT: After college, I was an early team member at KIPP DC College Preparatory in Washington, D.C., and founded the college counseling department. The school had the worst college graduation rates in the country, according to the Gates Foundation. Even though we were busy ensuring our students graduated and had the right postsecondary path for them, we hosted HIV screening. Ninety percent of the students got tested. Our approach was simple but not easy: Get the most popular student to get tested first. He set the bar. Everyone followed.

Healthcare has so much to learn from the user experience and insights in education. Fabric is predicated on these kinds of insights, trust building and teachable moments that have a clear, demonstrable impact and return.

TOP TWO PRIORITIES: First, hiring great teammates and supporting them. Second, shifting the paradigm from ineffective, legacy outreach of sending mail to outdated addresses and call centers autodialing while someone is in the middle of a shift at work to one of meeting families where they are, in the time they have and listening to understand their needs and priorities to create trusted, longitudinal relationships that improve their health and well-being.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: I would radically change the incentives. U.S. healthcare is a massive, profitable business, but it works terribly for most patients, particularly in the Black and Latino neighborhoods I've spent my career working in. We make it too complex, too difficult to navigate and too unfocused on who the actual customers are: patients and plan members.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "When Breath Becomes Air" humanizes the agony of illness, and "There Are No Children Here," decidedly not a healthcare book, about poor families' lives that should be required reading for everyone taking care of people who are dealing with Medicaid.

WORK-LIFE BALANCE: I don't know that I do. I work a lot. Co-founding a start-up is all-consuming (it's also filled with tremendous learning and gratification), but laundromats are busiest on the weekends, so I certainly don't work a 9-to-5. I can't say the system has to operate around those it serves and then work Monday through Friday, 9 to 5. But I do this work in deep partnership with my cofounder, Allister Chang, and a remarkable team building trusted, last-mile engagement to serve our country's busiest families.

I have an incredible husband and family (my three sisters and seven nieces and nephews), along with lifelong friends who keep me grounded and sane. And then there's always boxing and walks with my husband and dog, Pumpernickel.

DREAM DINNER COMPANION: Nelson Mandela. Having lived in Johannesburg in 2016 and seeing South Africa's diverse promise, as well as its deep inequities and all the country has been through and could be — Mandela's impact is everywhere.

Jamie Bullus, M.P.H.

Population health analyst on a dedicated health equity team, Optum Rx

I grew up in North Hanover, New Jersey, and attended the University of Oklahoma, where I earned a B.A. in journalism and mass communication. Graduating in 2009, I faced a challenging job market and decided to join AmeriCorps. I was placed at a federally qualified health center (FQHC) in Cleveland, working exclusively with uninsured patients. I chose to stay at the FQHC, moving into a role managing the refugee health program, which involved initial health screenings for all refugees resettled in the county and the opportunity to walk side by side with them through our health and social systems. This revelatory experience solidified my purpose, leading me to pursue a master's in public health from the University of Arizona and move into my current work focused on population health and health equity.

CAREER TURNING POINT: A pivotal moment in my career was when I realized that "the maps are the same." To me, what is often missing in health equity discussions is the acknowledgment that disparities in outcomes stem from systemic inequities, which trace back to structural and systemic racism and discrimination. That's why a heat map of elevated blood lead levels in children mirrors a map for COVID morbidities, diabetes prevalence, households in poverty, infant mortality and even high-speed internet availability. The maps are the same when inequities are ingrained in our systems.

TOP TWO PRIORITIES: Most of us working in healthcare are well aware that the current system is broken, but many interventions place the burden of change on the patients or consumers. This raises a fundamental question: Is our goal to improve the system for the people or to mold people to fit the system? When I first began my journey in quality improvement, I was introduced to the teachings of W. Edwards Deming, which reshaped my perspective of viewing healthcare as a broken system to a system perfectly designed to get the results that it gets. At Optum Rx, we are integrating health equity into the business model, and it is my priority to not only challenge us to look critically at aspects of our current operations that contribute to health inequities but to identify opportunities to design our systems to achieve the results we want: an elimination of health and healthcare disparities for all members we serve.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: One thing I would change about U.S. healthcare is the approach to primary prevention. The current narrative encourages prevention in order to maintain health, but this assumes people are already healthy. For many living in America today, the concept of prevention is a privilege.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "How We Do Harm: A Doctor Breaks Ranks About Being Sick in America" by Otis Webb Brawley, M.D. It spotlights the immoral financial drivers of treatment, or lack of treatment, and also the need to be critical and demand accountability within our fields and industry. I often use the first chapter, "Chief Complaint," as a preread to introduce people to the real meaning of the social determinants of health.

WORK-LIFE BALANCE: Understanding that I am fortunate to even consider maintaining a work-life balance helps me remain mindful of the need to be present in both areas and to prioritize accordingly, often day by day. Having children has refined my purpose, my desire to "plant trees in shade that I'll never sit in." However, I will say work-life balance is a process, not an outcome, and like all processes, requires continuous improvement.

DREAM DINNER COMPANION: My maternal grandmother passed away 13 years ago at the age of 86. Recently, I discovered a photo and a hint suggesting it was her high school photo. When I showed it to my mother, she told me it could not be her, as my grandmother never attended high school. This revelation surprised me. She was one of 12 children and born in the 1920s. I realized that the person I knew as my grandmother was only a tiny snippet of her full story, and I regret never asking more about her life. I believe everyone has had opportunities of greatness and courage that often go unnoticed simply because we do not ask, and I would like to hear her story.

Kayla E. Friend, Pharm.D.

Executive director, specialty digital and patient innovation, CVS Health

Growing up in Rhode Island, I was heavily influenced by my grandparents throughout my formative years. My grandmother's experience with the healthcare system inspired and then ultimately paralleled her early career training in hospitals and the challenges of navigating our complex healthcare system. I received my doctor of pharmacy (degree) from the University of Rhode Island College of Pharmacy and completed two years of postgraduate residency at the Connecticut Veterans Affair Health System with a focus in geriatrics. Passionate about solving problems and improving patients' experience by simplifying the complex, I joined CVS Health's innovation team in 2013, where my team and I are dedicated to improving patient experience and health outcomes.

CAREER TURNING POINT: There have been many pivotal moments in my career where I've leaned on the guidance of many mentors, leaders and friends. However, I find it essential to ensure I have space for self-reflection for critical decisions made at career turning points. The importance of filtering advice through my own lens of values and experience has helped ensure that my inner voice is heard and helped build self-confidence in my decision-making abilities. An early career example is when a close professor and mentor encouraged me to do a residency program post-graduation from my Pharm.D., helping me realize that it would set my entire career on a different trajectory. Another is when I declined applying for a promotional role while my dad was battling brain cancer, a decision that allowed me more time with him as well as an opportunity to finish a project in the role I held that was a pivotal initiative. I hope I have many more eureka points in my career to come, but this process of networking, surround-sound feedback, and applying self-reflection has been crucial during turning points in my career.

TOP TWO PRIORITIES: First, promoting a culture of collaboration to create sustainable solutions to simplify care. Second, unrelenting focus on patient experience by understanding their unique situations because healthcare is personal. Using 360-degree feedback, our team fosters an environment to better understand the patient experience, expand our perspective and build our empathy.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: My real answer is proprietary; however, I will say that we need to give patients more ability to lead their care decisions and to create systems and processes that allow them to self-serve in their own care.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: No longer being on the front line of healthcare daily, I seek any opportunities to see things through the patient's eyes. A moving book I read recently was "When Breath Becomes Air" by Paul Kalanithi, a memoir that reflects his journey as a promising young neurosurgeon who is faced with stage 4 lung cancer. Beyond the poignant life, purpose and mortality themes that he surfaces, his unique perspective on being both a part of the healthcare system and finding himself on the other side of the bedside as a patient reveals so authentically the power of the patient in decision-making and the importance of empathy in healthcare.

WORK-LIFE BALANCE: The first step for me was recognizing there is no such thing as work-life balance so that I'm not chasing an unrealistic expectation. Actually, I find it freeing to know that you cannot do it all; thus, it helps focus my decisions to decide what is most important. For me, it's more a process of continuous self-reflection and intentional decision-making. Anytime you choose to do something, there is another thing you are not doing, and so I intentionally choose to lean into different areas of my passions with continuous self-reflection and evaluation of need.

DREAM DINNER COMPANION: I cherish every dinner I get to have with my husband and three young children to share news about our day, talk through our challenges, laugh at their jokes, and look forward to events in the future.

Charles Lin, M.S.

Vice president of implementation and sales, Longevity Health, a clinical services company and institutional special needs plan (ISNP) for nursing home residents

I grew up in Guangzhou, China, where I earned my bachelor's degree in preventive medicine. I earned my master's of science in nutrition communication from Tufts University. When I worked in managed long-term care setting, I gained a deep understanding of the needs of vulnerable seniors and developed strategies tailored to their needs, which helped me tremendously in my career development. At Longevity Health, where our mission is to optimize the quality of life in people in long-term care by focusing on their individual needs, my role is both challenging and rewarding, as it allows me to bring patient-centered care to residents in nursing homes who need it most. My background in nutrition and health, combined with my commitment to improving senior care, drives my passion for making a positive impact in the lives of those I serve.

CAREER TURNING POINT: When I was an outreach worker at a community center in Manhattan for a short, four-month contracted work period, I witnessed firsthand the lack of proper care and support for seniors living in public housing) projects. Their stories and struggles suggested the deep health disparity among us, and it profoundly impacted my future career. It ignited a passion within me to not just excel in my professional role but to advocate for and contribute to improving the quality of care for the most vulnerable populations. This pivotal moment propelled me into my current position. Now, my work is driven by a commitment to ensuring that residents in nursing homes receive the comprehensive care they need and deserve.

TOP TWO PRIORITIES: Continue expanding the ISNP program footprint into all U.S. states and continue to deepen into more rural areas for those who have limited access to quality care.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Improve access to comprehensive care for nursing home populations. This involves increasing funding for Medicare programs, expanding access to specialized healthcare services, and implementing policies for nursing home operators that prioritize the well-being of their residents. By focusing on bringing high-quality care, we can help bridge gaps in the healthcare system and improve outcomes for those who need it most.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "The Healing of America: A Global Quest for Better, Cheaper, and Fairer Health Care" by T.R. Reid. The book illustrates differences in healthcare systems around the world and offers insights into how different countries achieve better outcomes. As someone who grew up in another country, I thinkthis book can widen our perspective and give us a new mindset of making the healthcare system better.

WORK-LIFE BALANCE: There are three main strategies I use to help me keep a work-life balance. First, understand the needs and prioritize tasks. Taking time to learn about and understand the needs of my family, my employer, and myself helps me to understand the full picture and have a solid base to make decisions on setting priorities. Second, trust and delegate. I learned to trust my staff and my colleagues, and understand what they are capable of doing, such as in leading projects and making decisions. Third, communicate with my boss. Having frequent, open conversations with my direct supervisor helps both of us to understand my work. When he understands the commitment and effort I put into my daily work, together we set realistic expectations of my work, and both of us aim to operate within the limits.

DREAM DINNER COMPANION: That would be my late father. My father passed away from cancer when I was in high school. He shared many life lessons during my childhood, and it was not until my adulthood that I had encountered those events and reflected (on) the meanings of the lessons. My career choice into medicine and health was deeply influenced by his passing. I would love to share who I am, what I have accomplished, and my goals in improving lives of others with him and let my father know how deeply he shaped my values and decisions.

Timothy O'Shea, Pharm.D., M.S.

Director, specialty pharmacy, Horizon Blue Cross Blue Shield of New Jersey

I was born in New Jersey and lived there until I attended and graduated from the Massachusetts College of Pharmacy and Health Sciences in Boston. I completed a postgraduate year one residency in managed care pharmacy and earned a master of science in health services administration from the University of Wyoming. I have worked for Horizon Blue Cross Blue Shield (BCBS) of New Jersey for over nine years. In my current role, I lead Horizon's strategy on specialty drug management, which includes pharmacy case management, site of care, biosimilar strategy, cell and gene therapy and more. In addition, I coordinate clinical programs with 15 health system value-based partners throughout New Jersey, including lower-cost drug alternatives, specialty initiatives, pharmacy gap closure and supporting Medicare Stars program. I have had work published in *Pharmacy Times*, *Managed Healthcare Executive*, the Magellan Rx Report and Relias Academy. I am currently an adjunct assistant professor at Rutgers University's Ernest Mario School of Pharmacy and am a member of the Academy of Managed Care Pharmacy's Educational Affairs Committee.

CAREER TURNING POINT: Growing up I always had an interest in science and then having the opportunity to work at a grocery store pharmacy in high school provided some early insights into developing a passion for pharmacy. In addition, throughout pharmacy school, I was able to complete rotations in a variety of clinical settings, which helped shape my future interests. In terms of general advice, I always come back to a phrase I heard many years ago, which is, "It costs nothing to be kind," which is something that I try to keep in mind as I strive to be an effective leader at work, husband and father.

TOP TWO PRIORITIES: My top priority as a leader at Horizon BCBS is to embody the spirit of the "Triple Aim," which focuses on improving health outcomes, managing the total cost of care and enhancing the member experience. Each of those three pillars forms the basis of the work my team and I do each and every day specific to prescription drugs.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: In an ideal world, there would be far less fragmentation in the current healthcare system. Data shows that polypharmacy (simultaneous use of five or more prescription drugs by one individual) has been steadily increasing over the past two decades. This can be exacerbated by individuals seeing multiple providers or specialists whose electronic medical records may not sync with each other, leading to potentially excessive or duplicative medication use. Shockingly, polypharmacy accounts for nearly 30% of all hospital admissions in the U.S.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: As an avid reader, I will call attention to two books. The first is "The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age" by Robert Wachter, M.D., which provides an insightful look into both the enormous advances and also stumbling blocks of healthcare technology. The second is "Biased: Uncovering the Hidden Prejudice That Shapes What We See, Think, and Do" by Jennifer Eberhardt, Ph.D., which covers meaningful insights into identifying and addressing our own biases.

WORK-LIFE BALANCE: As someone with two young children, [I know that] an effective work-life balance is something that is absolutely critical to manage on all sides. Certainly, time management and organization will always be key in all facets of life. But it's also important to realize that while work is important, there will always be something more to do at work. Unplugging and spending time with family and friends can never be understated.

DREAM DINNER COMPANION: From a historical perspective, it would be incredible to have a dinner conversation with George Washington, Benjamin Franklin and the other Founding Fathers of our country.

Prerak Parikh, Pharm.D.

Director, specialty clinical solutions, Prime Therapeutics LLC, a pharmacy benefits manager in Eagan, Minnesota

I am originally from India and moved to the United States at the age of 18 to pursue a career in pharmacy. While in pharmacy school, my mentor, Pranav Patel, introduced me to managed care pharmacy, and that led me to undertake an internship at a local health plan. I graduated from the University of Toledo with a Pharm.D. degree, driven by a profound commitment to effecting positive change within the healthcare industry.

As director, specialty clinical solutions at Prime, I use my extensive clinical expertise and business acumen in specialty drug management. I play an important role in shaping the medical drug strategy for health plan clients. Previously, I worked at Blue Cross Blue Shield of Michigan, where I specialized in Part B drug management, implementing cost-saving initiatives tailored for Medicare Advantage plans.

CAREER TURNING POINT: During my third year of pharmacy school, I deliberated whether to pursue a pharmacy residency. At that time, I was not a U.S. citizen and had only a one-year visa to secure employment post graduation. My academic adviser and mentor, Steven Martin, emphasized the critical role a residency would play in achieving my career aspirations. His pivotal advice, "Pursue your ideal career path, and life will align to make it happen," resonated deeply with me. I completed a one-year residency that served as a perfect gateway into managed care pharmacy, propelling me to where I am today.

TOP TWO PRIORITIES: Patient care stands as my foremost priority, both as a pharmacist and a leader. I consistently place patients at the heart of every decision and action, aligning closely with Prime Therapeutics' principle to provide the same care we would want for our loved ones. Positivity is contagious, so my priority is to create and maintain an optimistic environment where new ideas foster and meaningful solutions develop. As a coordinator for the specialty-focused Prime Therapeutics residency program, I mentor, train and coach the (next-generation) managed care pharmacy leaders.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Ensuring equitable healthcare access for all is paramount. If I were to advocate for a single improvement, it would involve dismantling barriers to healthcare through improving health literacy and expanding healthcare accessibility in rural regions.

A BOOK OR ARTICLE THAT EVERYONE WORKING IN HEALTHCARE SHOULD READ: I would highly recommend "Brain Rules" by John Medina. It presents 12 principles rooted in neuroscience, offering insights into how factors like exercise, sleep, stress and attention affect our cognitive abilities and daily performance. The book emphasizes the importance of aligning our lifestyles with our brain's natural processes to enhance productivity, learning and overall well-being.

Overall, the practical lessons from this book can enhance both patient care and professional practice in healthcare settings.

WORK-LIFE BALANCE: There is no such thing as perfect work-life balance. Work is an important part of our lives particularly with increasing "work from home" type arrangements. I try to bring my 100% to work every day, and when I am finished working, I equally commit to allocating my full attention to non-work aspects such as family, hobbies and leisure activities. This approach allows me to achieve harmony and fulfillment in life.

DREAM DINNER COMPANION: I would love to go to dinner with Mark Cuban. I find great inspiration in his journey of self-creation and unwavering focus on achieving his goals against all odds. It's amazing how he spread his wings into all sectors: technology, sports, television and his latest venture in health care. It would be great to gain firsthand perspectives on leadership, innovation, resilience and seizing opportunities in the business world.

Pleasant Radford Jr., MBA

Health Equity Officer at UCare, an independent, nonprofit health plan company with members in Minnesota and western Wisconsin

I grew up in Chicago in a home where my father was a vivid storyteller and my mother worked as a nurse at Ingalls Memorial Hospital. My early influences were my African American culture, my ancestral history, my Christian faith, my mom's career as a nurse and my dad's skill for storytelling. I attended the University of Illinois at Urbana-Champaign and received a B.S. in psychology and a B.A. in Spanish. Several years later, I attended the University of St. Thomas and received my MBA in finance. Throughout my life and career, healing and storytelling have played a crucial role in what my work is and how I do my work. As a Black man, I confront racism and microaggressions every day. Thus, I can empathize with other communities who endure unfair treatment in their daily life. Over the past three years, I've leaned into storytelling as a tool for healing. I am the host of the "Heart of Equity" podcast, where I talk with Black healthcare professionals to understand how they are advancing health equity in the Black community. Surprisingly, my role as a podcast host helps me in my current role as a health equity officer because as I learn about the unique stories within the Black communities and also more about myself and my story. This mutual sharing allows us all to find our paths toward individual and collective healing.

CAREER TURNING POINT: I worked with the Urban Health Initiative at the University of Chicago Medicine to help make the South Side of Chicago a model of health by 2025. We were asking different businesses to build on the South Side to improve health and economic vitality. The business owners would say, "I understand the health advantages, but let's talk about the ROI, profit margins, cost/benefit analysis, etc., so that we can sustain our business." Admittedly, I was unable to talk about the economic benefits, so I made the decision to pursue my MBA to understand business management and the role businesses play in enabling good health at the community level.

TOP TWO PRIORITIES: Climate change and housing. These two areas are having a growing impact on health and healthcare. My top two priorities in my organization are rebuilding trust in healthcare through community engagement and building the data architecture to collect, store and retrieve sexual orientation and gender identity data within our enterprise data warehouse.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Cost. A recent KFF survey showed that about half of U.S. adults say it is difficult to afford healthcare costs. Many are worried about unexpected bills, the cost of healthcare services (including out-of-pocket that are not covered by health insurance), prescription drug costs and long-term care services for themselves or for a family member. The lack of affordability can lead to people postponing care, which can worsen health conditions and outcomes.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "On Repentance and Repair: Making Amends in an Unapologetic World." I appreciate the book because it talks about repentance, atonement, forgiveness and repair from harm and our personal and collective responsibility to name and own harm, transform, accept consequences, apologize and make the required change to do better. This is particularly important in healthcare because patient harm is still too common.

WORK-LIFE BALANCE: I establish and protect boundaries so that I can be fully present at work and in life. Reducing multitasking and focusing on one thing at a time. Using my personal time off to unplug and recharge. Journaling so I can reflect on past actions, learn and make different choices. Creating accountability partners (i.e., friends, family, colleagues, etc.) to hold me accountable and help me achieve balance. Talking with a therapist to offer a new perspective and increase self-awareness.

DREAM DINNER COMPANION: I'd love to meet Rihanna. She is authentic, unapologetically confident, (and) a savvy businesswoman who consistently shows that you can build a successful international business (Fenty) that is inclusive of different races, backgrounds and experiences.

Anoop Raman, M.D., MBA

Chief medical officer, complex care, AbsoluteCare, an integrated healthcare provider headquartered in Columbia, Maryland

I was born in Queens, New York, and our family eventually made our way to suburban New Jersey. I went to Brown University, majored in economics, and spent a short time working at Lehman Brothers as an equities research analyst. I learned a powerful skill set on valuations and modeling and that Wall Street (unsurprisingly) did not fulfill my need to serve and make an impact. I decided to pursue an M.D. and MBA at Tufts University. After a few years, I had the opportunity to take a leave of absence from med school and work with my healthcare hero, Paul Farmer, M.D., at Partners In Health in Rwanda. There, I was able to combine my clinical and financial skill set and work with our teams to scale the work we were doing in four health centers to nearly 40 and help build the first-ever rural cancer center in East Africa. I returned to medical school and realized that I could never work in fee-for-service medicine — that my passion lay with improving the health of populations through value-based care. Now, at AbsoluteCare, caring for the most bio-psycho-socially complex members of the communities we serve, I am able to marry my penchant for business and passion for medicine.

CAREER TURNING POINT: Reading "Mountains Beyond Mountains," a book about Paul Farmer, opened my eyes to the depths of global health inequity and the ability of a small group of people to change the system. In the span of five years, from the late 1990s to the early 2000s, Partners In Health, thanks to the work of Paul Farmer and Jim Yong Kim, M.D., Ph.D., was able to change the public health paradigm on HIV care from, "We shouldn't deliver these medications to poor countries because these drugs are too expensive and poor people won't adhere to this daily regimen," to the World Health Organization's 3 by 5 initiative (3 million people on antiretrovirals by the year 2005) and the passage of PEPFAR (U.S. President's Emergency Plan For AIDS Relief), the world's largest, most effective and sustained global health program ever.

Reading about and then joining in this work at Partners In Health has shown me that big things are possible, and the antidote to despair is commitment and sustained action.

TOP TWO PRIORITIES: First, moving our health system toward value where clinicians are rewarded for better patient outcome. Second, restoring joy in practice for clinicians and patients, where providers enjoy their craft and patients feel that they are being treated as humans by people whom they know and whom they trust to care for them.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: The introduction of the computer into the exam room has deeply affected how the patients and providers connect to the detriment of human connection. I'm hopeful with the integration of new AI and language-learning models that technology will finally serve to help inform and connect providers and patients to see and hear each other once again, restoring humanity in healthcare.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "The Hot Spotters," an article in *The New Yorker*, by Atul Gawande was an article in *The New Yorker* that changed my life. It shows the power of focusing and addressing the needs of the highest-cost and highest-needs individuals. Too often, our health systems write off the sickest members of our populations as not impactable. What the article taught me and what my work at AbsoluteCare has shown me in real life is how transformative it can be when we match the intensity of care for our patients with the intensity of their need, not just in the hospital but in their community.

WORK-LIFE BALANCE: I wish I knew the answer to this question (about striking the right work-life balance). I think that life is full of seasons. Seasons to sprint and push hard at work, and seasons to recharge and be present for friends and family.

DREAM DINNER COMPANION: I would love to have dinner with Paul Farmer. He was my mentor, colleague and inspiration. The world lost him way too soon. It would be a chance to reconnect, to talk about the work I do with AbsoluteCare in cities across America and how I see it as part of his greater legacy, but most of all to say thank you again.

Ana Cristina Rivera, Esq.

Vice president of legal and compliance at Abarca Health, a pharmacy benefits manager and healthcare technology company

I was born and raised in San Juan, Puerto Rico. My grandfather, a radiologist, used to show me X-rays when I was little, which sparked my interest in healthcare. I went to Cornell University for undergrad and obtained my law degree from the University of Puerto Rico School of Law.

I began my career as a commercial litigation attorney, counseling clients in matters related to healthcare. In early 2014, after having worked as external counsel for a large national health plan, I was appointed the chief operations officer during the start-up of its operations of an on-island health plan. I later became associate vice president of government contracts, where I was the key liaison with the Puerto Rico Health Insurance Administration. This experience served as the foundation for my current role as vice president of legal and compliance at Abarca Health.

CAREER TURNING POINT: Having the opportunity to stand up a health plan and see it grow gave me a crash course on managed care operations and exposed me to parts of the business — clinical operations, claims, quality, compliance, actuarial, provider and member services, among others — that I wouldn't have had as an attorney. My role also afforded me the opportunity to draft and present before the state legislature position papers on legislative bills benefiting enrollees and payers and spearhead initiatives to improve the Puerto Rico Medicaid program.

TOP TWO PRIORITIES: As a legal and compliance leader at Abarca Health, one of my top priorities is enabling clients to succeed in this heavily regulated environment. The Inflation Reduction Act has brought significant changes to Medicare, while federal and state legislation related to pharmacy benefits has also increased. It's my job to help our clients navigate this complex climate and to work with our team to develop solutions that deliver a seamless and personalized experience for members, payers and providers.

From an organizational perspective, Abarca is driven by our corporate culture. Our team is dedicated to finding a better way in everything we do, including how we work together. I am focused on fostering collaboration by opening lines of communication, executing effective promise management and providing feedback to others.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Making healthcare more accessible and affordable should continue to be at the forefront of healthcare reform. I would begin by eliminating delivery models that reward quantity of services over quality of services. The U.S. healthcare system needs to accelerate its adoption of value-based models that reward whole-person and integrated care, improve patient outcomes and access to service and, ultimately, lower costs.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "The Emergency: A Year of Healing and Heartbreaking in a Chicago ER" by Thomas Fisher is a compelling memoir of an emergency room doctor working in South Side Chicago that poignantly addresses the topic of health equity and challenges of the U.S. healthcare system.

WORK-LIFE BALANCE: I like to begin my mornings with kickboxing or HIIT (high-intensity interval training) classes, which help me start the day with energy and focus. I also like to set "quiet time" at night during the week to read and take my mind off work. Weekends are my go-to time to spend some time with my family and friends. As the self-designated planner of my friend group, I like to coordinate outings to new restaurants and trips outside our hometown of San Juan. Traveling and immersing myself in new cultures is my top way for relaxing and disconnecting from work, including going to my happy place, St. John.

DREAM DINNER COMPANION: Michelle Obama. Though I've always admired her poise, grace, intelligence and the work she did as the first lady (particularly with the Let's Move initiative), the vulnerability she showed in her memoir, "Becoming," took my admiration for her to a whole new level. I'd love to have dinner with her to have a heart-to-heart about her experiences.

Nick Stepro

Chief product and technology officer, Arcadia, a healthcare data company headquartered in Boston

I grew up just north of Manchester, New Hampshire. I have bachelor's degree in economics and international relations from Tufts University. Before stepping into my current role, I held multiple positions at Arcadia, including senior vice president of product management and vice president of product development.

I work with large health systems and payers to design, implement and execute innovative clinical integration and business intelligence strategies to drive improved health outcomes and reduced system costs. I also work with leading technology service organizations, such as Amazon Web Services, on initiatives that enable healthcare transformation at cutting-edge scale and pace. I am currently focused on evolving the architecture of Arcadia's next-generation healthcare data platform to simplify the continuous acquisition and orchestration of petabytes of data and millions of patient records across the modern healthcare enterprise.

CAREER TURNING POINT: Early in my career, I devoted much of my time to implementing digital systems, like electronic health records. The industry converted paper work flows into digitized work flows but overindexed on putting data in, not getting insight out. Eventually, I helped customers figure out how to unlock data at scale and discovered amazing yields in terms of productivity improvements, identifying health disparities and creating long-term financial sustainability. Working closely with Michael Meucci, Arcadia's current president and CEO, I led efforts to incubate an idea that would eventually become the company's data analytics software platform.

TOP TWO PRIORITIES: With 30% of all data coming from the healthcare industry — an amount that's increased 5,000% since 2010 — efforts to harness, normalize and analyze vast volumes of health information require innovation beyond traditional tools. Under my leadership, Arcadia launched a next-generation healthcare data analytics platform in March of 2024 to further enhance healthcare organizations' abilities to harness big data, accelerate digital transformation and more rapidly adopt generative AI solutions.

Second, as an innovative leader dedicated to fostering a culture of innovation, I have championed the creation of the organization's AI innovation principles and rolled out foundational tooling across the business. My vision is to enable employees to focus on what matters most and use available tools and technology to increase productivity and reduce the time spent on repetitive administrative tasks.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Without question, reducing regulatory complexity and mandating meaningful data sharing. The pandemic put the industry closer to both, as an eye-opening moment that showed how quickly the industry can move when it needs to. However, too many innovators still face high barriers to entry and scale. Data is too siloed, and well-meaning regulations of quality and patient safety add friction.

A BOOK OR ARTICLE THAT EVERYONE WORKING IN HEALTHCARE SHOULD READ: "Stories From the Shadows: Reflections of a Street Doctor" by Jim O'Connell. One of my first customers was Boston Health Care for the Homeless Program, an organization led by O'Connell that provides healthcare with humanity to some of the community's most forgotten people. It's easy to get lost in the complexities of the U.S. healthcare system and forget the people it's built to serve. This collection of stories serves as a moving and inspiring reminder of healthcare's purpose.

WORK-LIFE BALANCE: I strive to stay flexible and listen and respond to how my brain is feeling. Instead of creating a strict on/off schedule, I listen closely to impulses and trust and respect that things will balance out. For example, I sometimes wake up on a Saturday morning itching to create new things and plug in to work. Other times, I find my mind tired and will take the afternoon off to work out, take a walk, or read the paper.

DREAM DINNER COMPANION: Many of history's brilliant people did a pretty good job at writing stuff down. Instead of the opportunity to dine with a celebrity genius (Mozart, Einstein, etc.), I'd opt to get a bite with his late grandfather or grandmother and enjoy love-filled conversation.

Abby Sugg, M.S.H.C.M.

Associate director of healthcare and public health programs at the Digital Medicine Society (DiMe), a global nonprofit and professional home for digital medicine

I grew up in Snow Hill, a small agricultural town in eastern North Carolina. Watching family and friends navigate the challenges of accessing quality healthcare initially sparked my interest in public health and its potential for rural communities. This passion led me to pursue a bachelor of science in public health at the University of North Carolina at Chapel Hill, followed by a master of science in healthcare management from Johns Hopkins Carey Business School.

My career spans working with payers, providers and IT start-ups, giving me valuable perspectives from across the industry and a comprehensive understanding of the healthcare ecosystem's intricacies. These experiences prepared me for my current role leading the Virtual First Care Coalition by DiMe. In this role, I convene leaders from all stakeholder groups to collaborate on innovative ways to improve outcomes, enhance access and deliver the most effective care possible for our patients. It's inspiring to come together with such a diverse group of leaders, from across the field, realizing that we are working toward similar goals.

CAREER TURNING POINT: A mentor once told me, "You don't have to always know the answer, but be willing to show up and learn." That's proven to be true countless times over the years, and this advice continues to serve as a reminder that the ultimate outcome won't always be determined by how much you know or how prepared you feel from the start but, rather, by your mindset and actions. Embracing a growth mindset has allowed me to navigate uncertainites with confidence, continually adapting and improving.

TOP TWO PRIORITIES: My top priorities are enhancing accessibility and fostering collaboration across the ecosystem to improve our healthcare system for everyone. Accessibility in healthcare extends beyond physical distance to include addressing financial concerns, building trusting relationships with patients and delivering clear, easy-to-understand information. Moreover, improving the healthcare system for everyone requires seamless communication and collaboration across sectors — from providers and payers to technology innovators and policymakers — to innovate effectively, address healthcare challenges comprehensively and, ultimately, meaningfully impact people's lives.

CHANGE ONE THING ABOUT U.S. HEALTHCARE: Lean into the mindset that "an ounce of prevention is worth a pound of cure." I would love to see a shift toward preserving health rather than a curative approach after a problem arises. This proactive approach would involve investing in a more holistic approach incorporating preventive medicine, health education and community-based initiatives to address potential health issues before they become severe, ultimately leading to a healthier population and a more sustainable healthcare system.

A BOOK OR ARTICLE THAT EVERYONE IN HEALTHCARE SHOULD READ: "The Healing of America" by T.R. Reid. This book examines global healthcare systems to discuss how other countries achieve broader coverage and better outcomes at lower costs than the United States. Although it was published in 2010, its message still resonates.

WORK-LIFE BALANCE: I strive to remain fully present in the moment. When I'm at work, I dedicate myself to the tasks at hand and diligently pursue my goals. However, I also prioritize time for activities I enjoy and are nonnegotiable in my schedule, which forces me to press pause and take breaks. Stepping away and returning later often boosts my productivity by fostering creativity and providing a fresh perspective.

DREAM DINNER COMPANION: Betty White, because she embodies resilience and versatility and found enduring success by staying true to her passion for making people laugh and embracing new opportunities throughout her life. Her ability to remain relevant and beloved by multiple generations is inspiring, and her humor, warmth and genuine love for what she does resonate deeply with me. I would love to learn from her experiences, hear her stories and soak in her wisdom about navigating life with grace and laughter.

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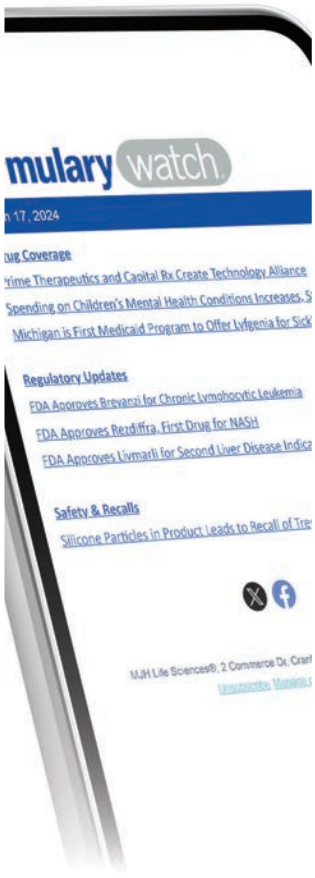

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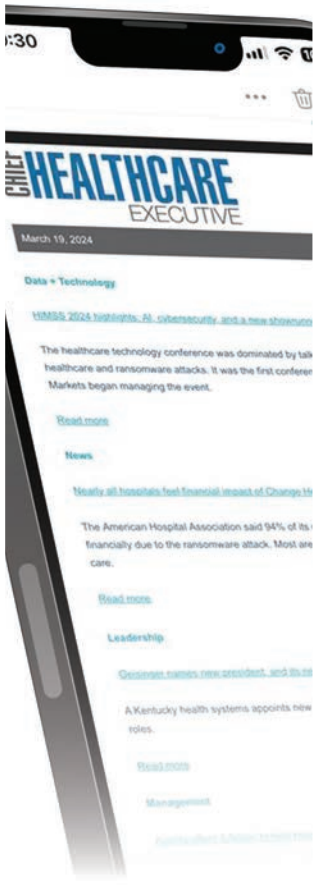

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States set up affordability boards to rein in drug costs

But Amgen is suing the Colorado board after it set payment limits on Enbrel.

By **SUSAN LADIKA**

As millions of Americans grapple with the high price of prescription drugs, a few states have established prescription drug affordability boards (PDABs), and others have legislation in the works that they hope will help rein in costs. However, one board is already facing legal action for its decisions.

"No drug is effective if you can't afford it or can't take it as prescribed," Tony Lourey, J.D., chair of the Minnesota PDAB, said during a webinar sponsored by the National Academy for State Health Policy. "It's a public health problem," added Benjamin N. Rome, M.D., M.P.H., assistant professor of medicine at Harvard Medical School in Boston. A survey by KFF found that more than one-fifth of adults have not filled a prescription because of the cost. Others have opted for over-the-counter medications instead, or they have cut pills in half or skipped doses because of costs.

The country's first PDAB was established in Maryland in 2019 to make prescription drugs more affordable for patients and the healthcare system, Andrew York, Pharm.D., J.D., its executive director, said during the webinar. Five people sit on the board and 26 on a stakeholder council representing various groups in the healthcare ecosystem.

Facing pushback

So far, 11 states have approved establishing PDABs, and about a dozen more are considering doing so. Colorado has a setup like Maryland's, with a five-member board and a 15-member advisory council, which were put in place in 2021. This year, it became the first in the country to try to curb prices — and the first to face a lawsuit as a result. "It's a highly litigious space because of the money involved," noted Rome.

A cost review by Colorado's PDAB in February found that the arthritis drug Enbrel (etanercept) was unaffordable, costing patients and their insurers up to $46,000 a year, *The Denver Post* reported. Patients' out-of-pocket costs averaged $2,295 in 2022 if they were covered by commercial insurance or a Medicare Advantage plan. The board decided to set an upper payment limit for reimbursement. Lila Cummings, deputy commissioner of health policy for the Colorado Department of Regulatory Agencies, said the state was setting a payment limit, not regulating price.

The PDAB's decisions apply to commercial plans, but self-insured employer-sponsored plans can opt in, Cummings said. In response to the decision to set an upper payment limit, Enbrel's manufacturer, Amgen, filed suit against Colorado's PDAB in March 2024 in federal District Court in Colorado, claiming, among other things, that the decision is unconstitutional, overrides federal patent law and violates the due process clause for drug manufacturers. This summer, the board decided that Stelara (ustekinumab), used to treat conditions such as Crohn's disease and plaque psoriasis, and Cosentyx (secukinumab), used for psoriatic arthritis, were unaffordable and began the process of setting an upper payment limit for them.

Other cost reviews

Maryland's PDAB recently selected six drugs for cost reviews, including four used to treat type 2 diabetes: Ozempic (semaglutide), Trulicity (dulaglutide), Farxiga (dapagliflozin) and Jardiance (empagliflozin). The board also is reviewing Skyrizi (risankizumab), and Dupixent (dupilumab), A cost review is a way to "look under the hood" at what goes into the cost of medications, York said. One option in Maryland would involve setting upper payment limits, which would control both what state and local governments would pay for prescription drugs, he noted.

Minnesota is now setting up its PDAB and will focus on the "most egregious drug families," Lourey said, where the price paid is "significantly in excess of the manufacturers' list price." Minnesota's board wants to examine where in the supply chain costs are being added, Lourey said. "The supply chain is so complex and convoluted," Lourey said, adding, "You can't fix a problem if you don't understand it and don't have the data to really unpack it." ◘

Susan Ladika *is an independent journalist in Tampa, Florida, and a frequent contributor to* Managed Healthcare Executive.

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What's changed in hospice in 2024?

Incorporating hospice care into Medicare Advantage didn't work out, and CMS is looking to identify low-quality providers.

By **DEBORAH ABRAMS KAPLAN**

Hospice use continues to grow as more older people have serious diseases, leading to the need for more palliative care. At the same time, CMS is adapting and trying new models to measure and improve quality and pay for services. The federal government spent $23.7 billion on hospice care in 2022, according to the latest Medicare Payment Advisory Commission (MedPAC) report, with at least 1.7 million Medicare beneficiaries receiving service. This includes nearly half of Medicare beneficiaries who died that year. Here's what to expect over the next year.

Hospice carve-out

Hospice has historically been carved out of the Medicare Advantage program, with Medicare paying for the service on its own. CMS started a pilot in 2021, allowing Medicare Advantage organizations to include hospice benefits in the Value-Based Insurance Design (VBID) model; however, it didn't go over well, with decreasing participation and some operational challenges. Part of that declining participation included UnitedHealthcare withdrawing from VBID as of the end of 2023. CMS recently announced that the hospice pilot will end Dec. 31, 2024.

"Medicare Advantage is not used to having anything to do with hospice and vice versa," says Tarrah Lowry, interim president of Trustbridge and chief operating officer of Empath Health.

Trustbridge, a hospice care provider, experienced its own difficulties with the carve-in due to difficulty with billing issues and information sharing when working with Humana, which was participating in the VBID and hospice carve-in model. Although they had a good relationship with Humana, Lowry said, some of Humana's information requests were too expensive to provide with the requested frequency. "It's bringing together systems not used to working together," she says.

LOWRY

Quality continues to be a CMS focus, although not everyone thinks the approach it is taking is the right one. The Special Focus Program (SFP) was part of the 2021 Consolidated Appropriations Act to identify poor performers using specific quality indicators. CMS finalized the methodology for inclusion in the SFP in the 2024 home health final rule. "They're concerned about low-quality care," says Patrick Harrison, J.D., senior director of regulatory and compliance at the National Hospice and Palliative Care Organization (NHPCO).

HARRISON

CMS is requiring larger and established hospices to provide data using the Consumer Assessment of Healthcare Providers and Systems (CAHPS) hospice survey. This survey aims to assess condition-level deficiencies, substantiated complaint findings, performance under the hospice care index and certain other hospice survey measures. On average, just under half of the hospices eligible to participate in the SFP have publicly reported CAHPS survey data, according to CMS.

Harrison says the methodology will be used to determine which hospices are potentially included in the SFP, and the bottom 10% of participating hospices nationwide will be publicly named in November 2024. He expects 700 hospices to fall into that category.

Although the goal is positive, Harrison says, with transparency helping consumers make informed choices about where to receive care, NHPCO and some other national hospice organizations are expressing serious concerns about the methodology. One reason is that it doesn't scale survey results and substantiated complaint scores based on hospice size. A hospice with a 500-person census and one adverse survey finding could be scored the same as a hospice with a 10-patient census and one adverse survey, he says. An unscaled score can penalize larger hospices and let smaller organizations with quality issues skate by, he notes,

GROWTH IN HOSPICE COVERED BY MEDICARE

	2010	2019	2021	2022	Avg. annual percent change, 2010-2019	Avg. annual percent change, 2019-2021
Spending (in billions)	$12.9	$20.9	$23.1	$23.7	5.5	5.1

Source: The Medicare Payment Advisory Commission 2024 Report to Congress, March 2024

Another concern, Harrison says, is that CMS is placing too much emphasis on CAHPS hospice survey scores. For hospices that provide survey information, the data are double-weighted. Slightly less than half of all SFP-eligible hospices report the data. This may provide a disincentive for hospices to report quality data, Harrison says. "We may be allowing other hospices to fly under the radar — [those] that aren't considered good quality [and] aren't willing to report quality data," he said.

Physician eligibility

Another change in the 2024 fiscal year is that CMS now requires that doctors who certify patients to be eligible for hospice care to be enrolled as a Medicare provider or be opted out in a valid manner. CMS wants oversight over physicians certifying to an illness and Medicare hospice benefits "to ensure there's no pattern of previous deficiencies, and to ensure they're really acting the way they should be in accordance with the requirements," Harrison says.

Although this is helpful overall, there are challenges in the CMS implementation, according to Harrison. That includes unclear and inconsistent guidance on billing and claims, in how hospices should report on their claims forms. Harrison is also concerned that by requiring the patient's designated attending physician to be Medicare certified, CMS may be restricting patient choice in who manages their care.

Three-quarters of hospice agencies are for-profit, up from one-third in 2000. MedPAC showed that for-profit hospice margins were 20.5% versus 5.8% for nonprofits in 2020. A RAND Corporation study showed lower-quality care in for-profit hospices, partly due to using fewer and less-skilled staff members.

As a hospice and palliative care organization, Trustbridge executives saw an uncertain future with potential payment changes, whether accountable care organizations begin paying for hospice or Medicare Advantage makes another run at it. "There are lots of changes that could happen, [which] means there's less money for hospices," Lowry says.

Trustbridge was recently acquired by Empath Health, becoming Florida's largest nonprofit postacute care provider — a move Lowry says was a good one. "It was important to us, our donors and our board to stay nonprofit," she says. Trustbridge gives away millions of dollars in free care each year, and they wanted to align with a nonprofit organization that supported that, says Lowry.

The Trustbridge acquisition was just one of many from the past 12 months, with 2023 seeing a decrease in deal volume. That was due partly to less low-hanging fruit and CMS' "license flipping" rule that requires hospices to retain their ownership for 36 months after obtaining a license.

Show me the money

The Medicare hospice 2024 fiscal year rate increase is 3.1%, which Lowry says was not enough of a boost. "The cost of living is going up substantially and we can't recruit enough nurses to fill positions," she said. For 2025, CMS proposed a 2.6% increase. "We're all disappointed," Lowry says, as it doesn't match the higher rates they're paying nurses and aides.

The 2024 annual hospice cap per patient was the same as the 2023 rate plus the 3.1% fiscal year increase, at $33,494.01. For 2025, the proposed rule caps per patient payments at $34,364.85, again using the 2024 figure plus the 2.6% increase.

What's coming up in 2025?

The next year's proposed rule is out, promising significant changes to the CAHPS survey.

"The goal is to simplify their surveys," and they'll do it by removing some questions from the survey and and simplifying some of the avaiable answers, says Harrison. They are also proposing to add a new online option for filling out the surveys so caregivers won't have to send their responses in by mail.

Although there are other changes in the 2025 rule, one that Lowry says is notable involves having hospice organizations provide payment information to CMS about expensive palliative care, such as dialysis, radiation and chemotherapy. "My organization pays for a lot of those things," she says. Medicare will not be reimbursing for those treatments right away, but the informaton gathering could be a first toward understanding the burden they place on hospsice providers and their budgets. ◘

Deborah Abrams Kaplan *writes about healthcare and other topics and is a regular contributor to* Managed Healthcare Executive.

K-Cast

Atopic dermatitis treatment: Past, present and future

As the understanding of atopic dermatitis has improved, treatment options have increased. One unresolved issue is when and if to start systemic therapy in young children.

In a seven-part *Managed Healthcare Executive* K-Cast video series, Lawrence Eichenfield, M.D., chief of pediatric and adolescent dermatology at Rady Children's Hospital-San Diego and a professor of dermatology at UC San Diego School of Medicine, discussed the current treatments for atopic dermatitis and the outlook for future therapies.

Treatment landscape and clinical burden

Over the past decade, new systemic therapies have been introduced, moving from a history of nonspecific immunosuppressive medicines to biologic agents and oral Janus kinase (JAK) inhibitors, Eichenfield said. The topical armamentarium has also changed with the addition of nonsteroidal medications to the traditional steroidal ones. Treatment choices have expanded because of an increased understanding of atopic dermatitis, its impact on people's lives and its association with both traditional allergic or atopic morbidities and nonatopic illness, Eichenfield explained.

The burden of atopic dermatitis is manifold, he continued. The rashes range from mild to severe. "Part of that clinical burden is the oozing, crusting, scaling and associated bleeding from scratching," said Eichenfield, noting that the itch from atopic dermatitis can have a major impact on people, negatively affecting sleep and the sleep of others, especially if the person affected is a child. The clinical burden also includes the development of associated allergies, including food allergies, asthma, allergic rhinitis and some rarer conditions. Eichenfield said there are also psychological consequences, including anxiety and depression, especially with more severe atopic dermatitis. "In most studies, if you ask people to rank the burden of the disease, they list itch as No. 1. But in my experience, rash is probably just as important," Eichenfield said.

Managing atopic dermatitis can get involved, which is another burden patients bear, he said. People are advised to bathe in certain ways, use moisturizers frequently and sometimes separate topical regimens for the face and the rest of the body. "It's a lot of work that has to be done depending on the severity of disease," Eichenfield said.

Overview of treatments

The usual strategy is to start with good skin care and bathing practices, including using a moisturizer after bathing, according to Eichenfield. If inflammation does not respond to moisturizers, the next step is anti-inflammatory agents, usually topical steroids. The first-line or second-line agents include calcineurin inhibitors, phosphodiesterase-4 inhibitors and a topical JAK inhibitor, Opzelura (ruxolitinib).

Eichenfield and his colleagues presented findings at the March 2024 American Academy of Dermatology Annual Meeting from a real-world effectiveness study of Opzelura that showed almost all of the 59 adult patients achieved clear or nearly clear skin within six months of therapy. More precisely, the average affected body surface area was reduced from 13.5% at the start of treatment to 5.7% (0%-20%) after treatment, and 62.7% (37 of 59 patients) had reduced disease severity, and 42.3% (25 of 59) achieved clear or almost clear skin. Physicians reported being satisfied with ruxolitinib cream monotherapy disease control for 91.5% of patients. Reasons to switch to ruxolitinib cream were loss of response/efficacy over time (33.3%), lack of long-term control (30.6%), patient requests (27.8%), and inadequate resolution of symptoms (22.2%).

Systemic therapy is the next step if more intense therapy is needed, Eichenfield said. Dupixent (dupilumab) was the first to be approved by the FDA. Originally approved just for adults, it is now approved for use in children and infants, Eichenfield noted. Other systemic agents mentioned by Eichenfield include Adbry (tralokinumab); lebrikizumab, which is approved in Europe but not by the FDA; and two oral JAK inhibitors, Cibinqo (abrocitinib) and Rinvoq (upadacitinib). There are also traditional immunosuppressive agents, such as methotrexate, although they are no longer used as much because of the selective biological agents.

"My decision-making on which therapies to use, topical therapies or systemic therapies, very much starts with my messaging to patients and families, which is that what I'm going for is minimal rash, minimal itch and minimal sleep disturbance," Eichenfield said.

Eichenfield said he considers how regional the atopic dermatitis is, the severity of the eczema quality and prior experience and responses to other medicines.

Eichenfield said the willingness of clinicians to use systemic therapy with the newer age of advanced systemic therapy is changing. He said that if someone has had an adequate trial of appropriate topical agents and there is inadequate control of signs and symptoms, "moving to a systemic agent right away certainly makes sense." He cautioned that the use of systemic therapy in younger children is "still pretty new" and that very few children under the age of 2 were included in the Dupixent trials.

Navigating health insurance

Eichenfield said that the prior authorization process can be a lot of work. He said he has learned as a front-line clinician to document cases with regular body surface area assessments and global scores. In specialty clinics, he uses the Eczema Area and Severity Index.

Eichenfield said he also advocates at a regional and national level so managed care companies know "what we consider to be state-of-the-art therapy." and don't put unnecessary burdens on patients "getting medicines that we think are going to markedly change their lives." Managed care organizations can implement reasonable evidence-based guidelines and best practices "by keeping their ear to the ground [and] having good personnel who are assessing what are considered to be the best therapies," Eichenfield said. There are cost-benefit issues, he acknowledged. "But," Eichenfield added, "in many cases, it comes down to if you had a family member with this disease state with this degree of severity … can they get the drug, and should they get the drug? If that's the case, we want to facilitate that." Eichenfield noted that it is also important to work with allergy, dermatology and pediatric dermatology professional organizations to ensure that their guidelines reflect the best practices.

VIDEO INSIGHTS

Elevating Atopic Dermatitis Care

Please scan the QR code to view the interview with Lawrence Eichenfield, M.D., and other interviews with experts on other subjects.

Patient response

Following patients' responses to therapy is part of good practice, said Eichenfield. Body surface area assessments can be done quickly, he said. Those assessments, along with global scores — if done routinely — can be helpful in underscoring successful responses to treatment for patients and, in pediatric cases, their families. Patients sometimes lose track of how bad their atopic dermatitis was before treatment, Eichenfield noted.

General questions are also important, in Eichenfield's opinion. " 'How are you doing? How's that itch? Is there sleep disturbance anymore? How's the disease impacting your life?' These are sort of standard questions that don't take that long to do in every visit and follow-up for eczema patients," Eichenfield said.

Clinicians also need to assess whether patients are experiencing any adverse events from medications, noted Eichenfield.

Looking ahead

Eichenfield said he is "incredibly proud" of the advances in understanding atopic dermatitis and the growing number of treatment options. There are still important questions that need answering, he said. "Probably the No. 1 question for me is, how will earlier therapy in the first few years of life impact the course of atopic dermatitis?" Eichnfield said. Some studies have suggested that introduction of treatment in the first few months of life might prevent atopic dermatitis or change its course and affect the development of food allergies. "I'm very excited about the next five to 10 years of atopic dermatitis research and how that translates into clinical practice," Eichenfield said, noting that data on the new wave of systemic therapies are suggestive of notable remission rates and a scenario whereby treatment for a relatively short period might mean remission with no need for further treatment.

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BRIEF SUMMARY

AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:

- individuals 60 years of age and older;
- individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

4 CONTRAINDICATIONS

Do not administer AREXVY to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of AREXVY *[see Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY.

5.2 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting.

5.3 Altered Immunocompetence

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY.

6 ADVERSE REACTIONS

In a clinical trial conducted in participants 60 years of age and older (NCT04886596), the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).

In a clinical trial conducted in participants 50 through 59 years of age (NCT05590403), the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Individuals 60 Years of Age and Older

The safety of AREXVY was evaluated in 15,845 vaccine recipients.

Study 1 (NCT04886596) is a placebo-controlled, Phase 3 clinical study conducted in Europe, North America, Asia, and the Southern Hemisphere (South Africa, Australia, and New Zealand), involving 24,966 participants, 60 years of age and older, who received AREXVY (n = 12,467) or saline placebo (n = 12,499). Study 2 (NCT04732871) is a non-placebo-controlled, open-label, Phase 3 clinical study conducted in Europe, North America, and Asia, involving 1,653 participants, 60 years of age and older, who received AREXVY. Study 3 (NCT04841577) is a non-placebo-controlled, open-label, Phase 3 clinical study conducted in New Zealand, Panama, and South Africa, involving participants 60 years of age and older who received 1 dose of AREXVY and FLUARIX QUADRIVALENT concomitantly (n = 442) or sequentially (n = 443).

At the time of vaccination in Study 1, the median age of the population was 69.0 years; 13,943 (55.8%) participants were 60 to 69 years of age, 8,978 (36.0%) participants were 70 to 79 years of age, and 2,045 (8.2%) participants were 80 years of age and older. The majority of participants were White (79.4%), followed by Black (8.7%), Asian (7.6%), and other racial/ethnic groups (4.3%); 5.5% were of Hispanic or Latino ethnicity; 51.7% were female. In Study 2, the median age of the population at the time of vaccination was 69.0 years; 820 (49.6%) participants were 60 to 69 years of age, 621 (37.6%) participants were 70 to 79 years of age, and 212 (12.8%) participants were 80 years of age and older. In Study 2, the majority of participants were White (67.8%), followed by Asian (30.0%), Black (2.0%), and other racial/ethnic groups (0.2%); 1.9% were of Hispanic or Latino ethnicity; 54.6% were female. In Study 3, the median age of the population at the time of the vaccination was 67.0 years; 519 (58.6%) participants were 60 to 69 years of age, 288 (32.5%) participants were 70 to 79 years of age, and 78 (8.8%) participants were 80 years of age and older, respectively. In Study 3, the majority of the participants were of mixed race (50.3%), followed by White (30.7%), and Black (16.0%); 34.7% were of Hispanic or Latino ethnicity; 51.5% were female.

Safety Data from Study 1

Solicited Adverse Reactions: : In Study 1, a subset of study participants (solicited safety set) was monitored for solicited adverse reactions using standardized paper diary cards during the 4 days (i.e., day of vaccination and the next 3 days) following a dose of AREXVY or placebo; 879 participants received AREXVY and 874 participants received placebo. The other study participants did not prospectively record solicited reactions on a diary card but may have reported them as unsolicited adverse reactions.

The reported frequencies of specific solicited local (administration site) and systemic adverse reactions (per participant) are presented in Table 1.

Table 1. Percentage of Participants with Solicited Local Adverse Reactions and Systemic Adverse Reactions within 4 Days of Vaccination in Individuals 60 Years of Age and Older (Solicited Safety Set with 4-Day Diary Card)

Local Adverse Reactions	AREXVY % N = 879	Placebo[a] % N = 874
Pain, Any[b]	60.9	9.3
Pain, Grade 3[b]	1	0
Erythema, >20 mm	7.5	0.8
Erythema, >100 mm	0.2	0
Swelling, >20 mm	5.5	0.6
Swelling, >100 mm	0.2	0
Systemic Adverse Reactions	**N = 879**	**N = 878**
Fatigue, Any[c]	33.6	16.1
Fatigue, Grade 3[c]	1.7	0.5
Myalgia, Any[c]	28.9	8.2
Myalgia, Grade 3[c]	1.4	0.3
Headache, Any[c]	27.2	12.6
Headache, Grade 3[c]	1.3	0
Arthralgia, Any[c]	18.1	6.4
Arthralgia, Grade 3[c]	1.3	0.6
Fever, ≥38.0°C/100.4°F[d]	2.0	0.3
Fever, >39.0°C/102.2°F[d]	0.1	0.1

N = Exposed set for solicited safety set included all participants with at least 1 documented dose.

[a] Placebo was a saline solution.

[b] Any grade pain: Defined as any pain neither interfering with nor preventing normal everyday activities (Grade 1), painful when limb is moved and interferes with everyday activities (Grade 2), or significant pain at rest and prevents normal everyday activities (Grade 3).

[c] Any grade fatigue, myalgia, headache, arthralgia: Defined as event easily tolerated (Grade 1), interfering with normal activity (Grade 2), or preventing normal activity (Grade 3).

[d] Temperature taken by any route (oral, axillary, or tympanic).

In the solicited safety set, the local administration site adverse reactions reported with AREXVY had a median duration of 2 days, and the systemic adverse reactions reported with AREXVY had a median duration ranging between 1 and 2 days.

Unsolicited Adverse Events: In all participants from Study 1, unsolicited adverse events were monitored using paper diary cards during the 30-day period following vaccination (day of vaccination and the next 29 days).

Among participants in the solicited safety set, (AREXVY, n = 879 or placebo, n = 878), unsolicited adverse events occurring within 30 days after vaccination were reported in 14.9% and 14.6% of participants who received AREXVY and placebo, respectively.

In the exposed set, 24,966 participants 60 years of age and older, received at least 1 dose of AREXVY (n = 12,467) or placebo (n = 12,499). Unsolicited adverse events occurring within 30 days of vaccination were reported in 33.0% and 17.8% of participants, respectively. The higher frequency of reported unsolicited adverse events among participants who received AREXVY, compared to participants who received placebo, was primarily attributed to events that are consistent with adverse reactions solicited among participants in the reactogenicity subset. Within 30 days after vaccination, atrial fibrillation was reported in 10 participants who received AREXVY and 4 participants who received placebo (of which 7 events in AREXVY arm and 1 event in placebo arm were serious); the onset of symptoms ranged from 1 to 30 days post vaccination. The currently available information on the atrial fibrillation is insufficient to determine a causal relationship to the vaccine. There were no other notable patterns or numerical imbalances between groups for specific categories of unsolicited adverse events.

(*continued on next page*)

Serious Adverse Events: In Study 1, participants were monitored for all serious adverse events (SAEs) that occurred during the 6-month period following administration of AREXVY (n = 12,467) or placebo (n = 12,499).

SAEs with onset within 6 months following vaccination were reported at similar rates in participants who received AREXVY (4.2%) or placebo (4.0%). Serious events of atrial fibrillation were reported in 13 participants who received AREXVY and 15 participants who received placebo within 6 months after vaccination.

Deaths: From vaccination through the first analysis of the ongoing Study 1, adverse events leading to death were reported for 49 participants (0.4%) who received AREXVY (n = 12,467) and 58 participants (0.5%) who received placebo (n = 12,499). Based on available information, there is no evidence of causal relationship to AREXVY. Causes of death among participants were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases: In Study 1, participants were monitored for all potential immune-mediated diseases (pIMDs) that occurred during the 6-month period following administration of AREXVY (n = 12,467) or placebo (n = 12,499).

New onset pIMDs or exacerbation of existing pIMDs within 6 months following vaccination were reported for 0.3% of participants who received AREXVY and 0.3% of participants who received placebo. There were no notable imbalances between study groups in individual pIMDs reported.

Serious Adverse Events Reported From Other Studies

Study 2: Guillain-Barré syndrome beginning 9 days after AREXVY vaccination was reported in a participant enrolled in a study site in Japan.

Study 3: Acute disseminated encephalomyelitis (ADEM) was reported in 2 participants enrolled in a study site in South Africa; the onset of the symptoms was 7 and 22 days post vaccination, respectively. One event was fatal and the other non-fatal. These participants received AREXVY concomitantly with FLUARIX QUADRIVALENT. For both events, magnetic resonance imaging and cerebrospinal fluid analyses were not performed.

Individuals 50 through 59 Years of Age

Study 4 (NCT05590403) was a Phase 3, observer-blind, randomized, placebo-controlled study conducted in Argentina, Canada, Germany, Japan, the Netherlands, Poland, Spain, and the U.S., in participants 50 through 59 years of age (n = 769 AREXVY; n = 383 saline placebo), including a subset of participants with stable chronic medical conditions associated with an increased risk for LRTD caused by RSV defined as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease (n = 386 AREXVY; n = 191 saline placebo). The study also enrolled participants 60 years of age and older (n = 381 AREXVY) *[see Clinical Studies (14.2) of full prescribing information]*.

At the time of vaccination in Study 4, the median age was 57 years for the entire study population and 55 years for the age group 50 through 59 years. The racial/ethnic and sex distribution of study participants were similar in the two age groups. The majority of participants were White (83.8%), followed by Asian (11.2%), Black (3.3%), and other racial/ethnic groups (1.7%); 14.3% were of Hispanic or Latino ethnicity; 52.1% were female.

In Study 4, all participants were monitored for solicited adverse reactions during the 4 days following vaccination (i.e., day of vaccination and the next 3 days) and for unsolicited adverse events, during the 30-day period following vaccination (day of vaccination and the next 29 days), using standardized paper diary cards. Participants were monitored for all SAEs and for all pIMDs (serious and non-serious cases) that occurred during the 6-month period following vaccination. Among participants, 99.2% have completed at least 6 months of follow-up following vaccination.

Solicited Adverse Reactions: The reported frequencies of specific solicited, local (administration site), and systemic adverse reactions among participants 50 through 59 years of age are presented in Table 2.

Table 2. Percentage of Participants with Solicited Local Adverse Reactions and Systemic Adverse Reactions within 4 Days of Vaccination from Study 4 (Exposed Set)

Local Adverse Reactions	AREXVY 50 through 59 Years of Age % N = 756	Placebo[a] 50 through 59 Years of Age % N = 379
Pain, Any[b]	75.8	12.1
Pain, Grade 3[b]	3.4	0.3
Erythema, >20 mm	13.2	0.5
Erythema, >100 mm	0.5	0
Swelling, >20 mm	10.4	0.8
Swelling, >100 mm	0.1	0
Systemic Adverse Reactions	**N = 756**	**N = 380**
Fatigue, Any[c]	39.8	18.2
Fatigue, Grade 3[c]	2.8	0.8
Myalgia, Any[c]	35.6	9.7
Myalgia, Grade 3[c]	2.5	0.5
Headache, Any[c]	31.7	16.8
Headache, Grade 3[c]	2.6	1.1
Arthralgia, Any[c]	23.4	7.9
Arthralgia, Grade 3[c]	1.7	0.8
Fever, ≥38.0°C/100.4°F[d]	3.2	1.1
Fever, >39.0°C/102.2°F[d]	0.1	0.5

N = Exposed set included all participants with at least 1 documented dose and with completed diary card.
[a] Placebo was a saline solution.
[b] Any grade pain: Defined as any pain neither interfering with nor preventing normal everyday activities (Grade 1), painful when limb is moved and interferes with everyday activities (Grade 2), or significant pain at rest and prevents normal everyday activities (Grade 3).
[c] Any grade fatigue, myalgia, headache, arthralgia: Defined as event easily tolerated (Grade 1), interfering with normal activity (Grade 2), or preventing normal activity (Grade 3).
[d] Temperature taken by any route (oral or axillary).

The rates of solicited local and systemic adverse reactions (Table 2) were similar in participants 50 through 59 years of age either with or without pre-defined, stable, chronic medical conditions associated with an increased risk for LRTD caused by RSV.

Overall, the median duration of solicited local adverse reactions and solicited systemic adverse reactions after AREXVY vaccination was 2-3 days and 1-2 days, respectively.

Unsolicited Adverse Events: Unsolicited adverse events within 30 days after vaccination were reported in 13.8% of participants, 50 through 59 years of age, who received AREXVY (N=769) compared to 12.0% of participants who received placebo (N=383). Within 30 days after vaccination, there were no cases of atrial fibrillation reported in participants 50 through 59 years of age.

Serious Adverse Events: In Study 4, participants were monitored for all SAEs that occurred during the 6-month period following administration of AREXVY (N=769) or placebo (N=383). Among participants 50 through 59 years of age, SAEs with onset within 6 months post vaccination were reported in 2.3% of those who received AREXVY and 2.1% of those who received placebo.

Deaths: Among participants 50 through 59 years of age, adverse events leading to death within 12 months after vaccination were reported for 4 (0.5%) participants who received AREXVY (N=769) and 1 (0.3%) participant who received placebo (N=383). None of these deaths were considered causally related to AREXVY.

Potential Immune-Mediated Diseases: In Study 4, participants were monitored for all pIMDs that occurred during the 6-month period following administration of AREXVY (N=769) or placebo (N=383). Among participants 50 through 59 years of age, new onset pIMDs or exacerbation of existing pIMDs with onset within 6 months post vaccination were reported in 0.5% of those who received AREXVY and 0.3% of those who received placebo. There were no notable imbalances between study groups in individual pIMDs reported.

(*continued on next page*)

AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)
BRIEF SUMMARY (cont.)

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

AREXVY is not approved for use in persons <50 years of age.

In a clinical study that enrolled pregnant individuals who received an investigational unadjuvanted RSV vaccine that contained the same RSVPreF3 antigen as AREXVY, an increase in preterm births was observed compared to pregnant individuals who received placebo (sucrose reconstituted with saline). *[See Use in Specific Populations (8.1) of full prescribing information.]*

Data

Human Data: There are no data on the use of AREXVY in pregnant individuals. In a randomized controlled clinical trial that enrolled pregnant individuals in a 2:1 ratio, 3,557 received an investigational unadjuvanted RSV vaccine that contained the same RSVPreF3 antigen as AREXVY and 1,771 received placebo (sucrose reconstituted with saline) at 24 to 34 weeks gestation. In the vaccine and placebo groups, 6.81% and 4.95% of preterm births were reported.

8.2 Lactation

Risk Summary

It is not known whether AREXVY is excreted in human milk. AREXVY is not approved for use in persons <50 years of age. No human or animal data are available to assess the effects of AREXVY on the breastfed infant or on milk production/excretion. *[See Use in Specific Populations (8.2) of full prescribing information.]*

8.4 Pediatric Use

Evidence from an animal model strongly suggests that AREXVY would be unsafe in individuals younger than 2 years of age because of an increased risk of enhanced respiratory disease. Safety and effectiveness in individuals 2 years through 17 years of age have not been established.

8.5 Geriatric Use

Of the total number of participants (N = 24,966) who received AREXVY or placebo in Study 1 (NCT04886596), 13,943 (55.8%) were 60 to 69 years of age, 8,978 (36.0%) were 70 to 79 years of age, and 2,045 (8.2%) were 80 years of age and older *[see Adverse Reactions (6.1), Clinical Studies (14.1) of full prescribing information].*

Manufactured by **GlaxoSmithKline Biologicals**
Rixensart, Belgium, U.S. License 1617, and
Distributed by **GlaxoSmithKline**
Durham, NC 27701

June 2024 ARV:2BRS

PMUS-RSAJRNA240010 June 2024
Produced in USA.

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

GSK

NOW APPROVED FOR EXPANDED PATIENT POPULATION

The first and only RSV vaccine for adults 50-59 YOA at increased risk* for RSV-LRTD

***Medical conditions defined as:** chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic liver disease, or chronic kidney disease.

To learn more, visit AREXVYhcp.com

Indication

AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:

- individuals 60 years of age and older;
- individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

Important Safety Information

- AREXVY is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of AREXVY
- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of AREXVY
- Syncope (fainting) may occur in association with administration of injectable vaccines, including AREXVY. Procedures should be in place to avoid injury from fainting

Important Safety Information (cont'd)

- Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to AREXVY
- In adults 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%)
- In adults 50 through 59 years of age, the most commonly reported adverse reactions (≥10%) were injection site pain (75.8%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), arthralgia (23.4%), erythema (13.2%), and swelling (10.4%)
- There are no data on the use of AREXVY in pregnant or breastfeeding individuals. AREXVY is not approved for use in persons <50 years of age
- Vaccination with AREXVY may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for AREXVY on the adjacent pages.

IS YOUR PLAN READY? **ACTIVATE COVERAGE NOW**

Reference: Prescribing Information for AREXVY.

RSV-LRTD=respiratory syncytial virus-associated lower respiratory tract disease; YOA=years of age.