

Clinical Practice and Business Updates

**Aducanumab (Aduhelm) treatment for Alzheimer’s Disease approved by FDA under accelerated approval pathway**

Aducanumab (Aduhelm) is a monoclonal antibody that targets aggregated forms of beta-amyloid in the brain and was [approved](#) by the U.S. Food and Drug Administration on June 7, 2021 for the treatment of Alzheimer’s disease. Aducanumab was approved under the [accelerated approval pathway](#), which requires the company to conduct a Phase IV trial to verify clinical benefit.



Conflicting results for aducanumab were reported in two unpublished Phase 3, randomized, double-blind, placebo-controlled studies (EMERGE and ENGAGE trials). Both trials were terminated early after a [futility analysis](#). In the clinical trials, brain swelling, microhemorrhages, and superficial siderosis [ARIA (-E and/or -H)] was observed in [41% of patients](#) treated with aducanumab.

Several entities have expressed concern about the accelerated approval of this new treatment. To address the approval and subsequent concerns, we have developed a [Member FAQ](#) for patients to help answer general questions about aducanumab.

The FDA also updated the original prescribing information for aducanumab in July:

**Prescribing information – June 7, 2021**

INDICATIONS AND USAGE  
ADUHELM is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). (1)

**Prescribing information – July 7, 2021**

RECENT MAJOR CHANGES  
Indications and Usage (1) 7/2021

INDICATIONS AND USAGE  
ADUHELM is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). (1)

If you have questions about this treatment and would like to talk with a medical director, please email your provider services consultant and we will connect you with a medical director to discuss it.



**Third party liability – researching pedestrian and bicycle injuries**

The Kaiser Permanente Other Party Liability department will research pedestrian and bicycle injuries to see if a vehicle is involved. Every year

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approximately 76,000 pedestrians and bicyclists suffer injuries when they are struck by a moving vehicle.

In Washington, the first level of medical payments coverage comes from the driver's automobile policy. The second level of coverage comes from the pedestrian's or bicyclist's own automobile policy. This often comes as a surprise to our members, as they usually don't realize their insurance covers them for this type of auto accident as well. It doesn't matter whose fault it was to use these benefits; auto insurances are primary to all Kaiser Permanente health plans if they offer this coverage. Those medical benefits don't require co-pays, co-insurance or deductibles. Plus, the member may be eligible for additional compensation.

If you have questions, please give the Other Party Liability Department a call at (866) 783-9594.

### **Mental Health and Wellness referrals easier to request on Affiliate Link**

With the launch of the Provider Portal, the mental health and substance use disorder referrals for contracted providers were made to mirror that of our fax requests. However, we have determined that less information is needed if the provider uses the online Provider Portal. Mental Health leadership has worked with the Affiliate Link build team to develop a separate referral for WPMG and KP internal providers.



### **What is Changing?**

The primary change you will see in the mental health (MH) and substance use disorder (SUD) referrals is the reduction in questions required to submit a referral request. Additionally, we are adding an Addiction Medicine Consultation and Esketamine option for mental health providers.

- Simplification of MH and SUD referrals
- Esketamine added to referral for MH/SUD providers
- Addiction Medicine Consultation added to referral for MH/SUD providers

### **Who is Impacted?**

- Kaiser Permanente contracted MH/SUD providers
- Kaiser Permanente contracted non-MH/non-SUD providers (primarily Primary Care)

### **What is the Go-live Date for New Referral Launch?**

MH Referral for non-MH/non-SUD providers	6/2/2021
MH Referral for MH/SUD providers	6/16/2021
SUD Referral for non-MH/non-SUD providers	6/30/2021
MH Referral for MH/SUD providers	6/30/2021

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We have two job aids to assist you with these submitting referrals via Affiliate Link:

- [Mental Health & Wellness Providers Requesting Authorizations via Referral/Order Entry](#)
- [Mental Health & Wellness/Chemical Dependency Facilities – Requesting Authorizations Via Manual/Exception Referral Entry](#)

If you need further assistance with these types of referrals, please call the Provider Assistance Unit at 1-888-767-4670 or email your Provider Services consultant.



### **New Chronic Opioid Therapy and Combination Opioid and Benzodiazepine Patient Education Campaign**

Overdose involving the use of opioids continues to be a serious health problem in the United States. In 2019, the CDC estimated that over 70% of the more than 70,000 drug overdoses that year involved the use of an opioid.<sup>1</sup> Kaiser Permanente is committed to supporting safer opioid

prescribing practices and improving patient education in an effort to reduce overdose related to prescribed opioids.

In late 2020, Kaiser Permanente conducted a small targeted pilot study based on literature suggesting that patient education may have a small, but appreciable impact on deprescribing of high risk medications.<sup>2</sup> This July, Kaiser Permanente will expand this lettering campaign to include all adult Kaiser Permanente members identified as being on chronic opioid therapy with an average milligram morphine equivalent (MME) dose of 50 and members on any dose of opioid with overlapping claims with benzodiazepines resulting in a 30 or more days of cumulative overlap. Members using opioids for cancer pain or on hospice or palliative care services are to be excluded from this mailing. Copies of these letters may be found here: [Chronic Opioid Therapy Letter](#), [Combination Opioid and Benzodiazepine Letter](#).

Impact to providers: We anticipate that members who get this letter will respond appropriately by reaching out to their prescriber to ask for further guidance. Here are a few resources that may be helpful to prescribers as they work with their patients towards safer care plans:

- Kaiser Permanente Chronic Opioid Therapy Guideline: <https://wa-provider.kaiserpermanente.org/static/pdf/public/guidelines/opioid.pdf>
- Kaiser Permanente Benzodiazepine and Z-drug Safety Guideline: <https://wa-provider.kaiserpermanente.org/static/pdf/public/guidelines/benzo-zdrug.pdf>
- Please ensure that naloxone has been discussed and prescribed for these patients.
- The following non-pharmacologic treatments are important and valuable options if you discuss a tapering plan with your patient: Physical therapy, exercise, movement therapies, such as PT, yoga, and tai chi, mental health therapies, such as CBT, ACT, and DBT, complementary/integrative, such as acupuncture, chiropractic, massage, naturopathy, and herbal treatments, and patient education and self-management courses, such as Better Choices,

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Better Health (members can register at this link: <https://enroll-kpwa1.selfmanage.org/>) or CBT for pain.

- The Six Building Blocks program at [www.improvingopioidcare.org](http://www.improvingopioidcare.org). A free program supporting clinics in implementing best practices for opioid management.

We recognize that it can be a struggle to help patients with chronic pain to minimize their risks as we respond to their expectations for treatment. It's our hope that these resources and this mailing will support prescribers in this important work.

### References:

1. CDC website: <https://www.cdc.gov/drugoverdose/deaths/index.html>
2. Tannenbaum, c, et al. "Reduction of Inappropriate Benzodiazepine Prescriptions Among Older Adults Through Direct Patient Education. The EMPOWER Cluster Randomized Trial." *JAMA Intern MED*.2014;174(6):890-898.

### Updated Migraine and Tension Headache Guideline includes new options for prophylaxis

Kaiser Permanente's [Migraine and Tension Headache Guideline](#) has been reviewed and updated. New in this edition:

- Additional **complementary and alternative therapies** may be considered for preventing both tension and migraine headaches, including biofeedback, cognitive behavioral therapy, relaxation training, mindfulness, and yoga.
- **Melatonin, zinc, and vitamin D** may be considered for migraine prophylaxis.
- **Butterbur and co-enzyme Q10** are no longer recommended for migraine prophylaxis.
- **Occipital nerve block** may be used as an adjunct treatment to reduce the frequency and intensity of migraine headaches.
- **Botulinum toxin or calcitonin gene-related peptide (CGRP)** monoclonal antibodies may be given to reduce the frequency and intensity of migraine headaches. Administration of these treatments is limited to Neurology providers. Adequate trial of at least 3 other formulary preferred prophylactic migraine medications and documentation of no medication overuse headache may be required for health plan coverage.



### Questions?

[Katie Paul, MD, MPH](#), Clinical Lead, Clinical Improvement & Prevention  
[Avra Cohen, MN, RN](#), Guideline Coordinator

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### Upcoming Changes



Please check our provider site on a regular basis for provider manual changes and updates. We communicate changes to the [provider manual](#) in the [Provider eNews](#) and in our [Provider Updates](#) for your convenience. However, it is your responsibility to remain updated on our changes by visiting our site regularly for updates on our policies and procedures. Thank you for your partnership in the care of our members!

Recently updated [payment policies](#):

- [Telemedicine Services \(Commercial\)](#)

[Letters to providers](#):

#### [Hospital Acquired Conditions, Adverse & Never Events](#)

**Effective July 15, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) will not separately reimburse for Hospital-Acquired Conditions (HAC), Never or Adverse Events. Acute care inpatient hospitals are not allowed to receive or retain any reimbursement for inpatient services related to CMS-identified HACs, Adverse or Never Events. All participating acute care inpatient hospitals are required to hold members harmless for any inpatient services related to CMS-identified HACs and Never Events.

#### [Allergen Immunotherapy](#)

**Effective July 15, 2021**, when benefits allow, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) will reimburse Allergy Immunotherapy practice expenses, billed utilizing CPT code 95165, up to a maximum of 150 doses per calendar year, per patient.

#### [Modifiers JA and JB](#)

**Effective July 15, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente), when benefits allow, will reimburse for medications that have one J Code for multiple routes of administration. To allow for proper monitoring of dose and treatment frequency, the JA or JB modifier must be present on the claim to indicate the route of administration as either intravenous or subcutaneous.

#### [Chromoendoscopy and Narrow Band Imaging](#)

**Effective August 15, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) will not separately reimburse for chromoendoscopy, chromoscopy, chromocolonoscopy or narrow band imaging as a part of services provided during a diagnostic or surveillance colonoscopy or endoscopy.

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### [Changes to medical necessity review criteria for certain elective surgical procedures](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) will implement site of care review criteria for certain elective surgical procedures for non-Medicare members. This will be implemented using a phased approach, starting with Benton, Kitsap, Spokane, and Whatcom counties.

### [Changes to medical necessity review criteria for breast MRI](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating medical necessity criteria for breast MRI.

### [Changes to medical necessity review criteria for coronary artery calcium](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating the clinical review criteria for coronary artery calcium (CAC) scoring for non-Medicare members.

### [Changes to medical necessity review criteria for cochlear implants](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating the clinical review criteria for cochlear implants for non-Medicare members.

### [Changes to medical necessity review criteria for enteral formula](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating the clinical review criteria for enteral formula for non-Medicare members.

### [Changes to medical necessity review criteria for Intensity Modulated Radiation Therapy \(IMRT\)](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating the clinical review criteria for IMRT for non-Medicare members.

### [Changes to medical necessity review criteria for total joint arthroplasty](#)

**Effective August 1, 2021**, Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) are updating the medical necessity criteria for elective total hip, total knee and total shoulder replacements or revisions performed in a hospital inpatient status for all members.

Please see our [COVID-19 Provider Resources page](#) on our [provider website](#) for helpful coverage and claims resources.

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### CME and Workshop Opportunities



#### Continuing Education Opportunities

Kaiser Permanente Washington offers a variety of continuing medical education courses throughout the year, detailed on our [CME Catalog page](#). Check out current opportunities below!

#### **Upcoming CME Courses**

Courses presented live via MS Teams

Contact: [Christopher.J.Scott@kp.org](mailto:Christopher.J.Scott@kp.org)

[Course Information and Registration](#)

<u>DATE</u>	<u>COURSE</u>
July 16, 2021	Suboxone: Half-Half Buprenorphine Waiver
September 21, 2021	Evidence Based Medicine in a Time of COVID-19: The Evolution of EBM During a Pandemic
October 6, 2021	Women's Health for Primary Care
October 21, 2021	Diabetes for Primary Care 2021
January – December 2021	Suicide Prevention 2021 (online - free)
January 26, 2022	Orthopedics and Sports Medicine for Primary Care

### Medicare Formulary Updates

#### **Product Removal: Lyrica CR TB24 82.5 MG, 165 MG, 330 MG; AZOPT SUSP 1 %**

Effective July 1, 2021, the brand-name drug Lyrica CR TB24 82.5 MG, 165 MG, 330 will be removed from the Kaiser Permanente Medicare Part D Drug List as generic alternative is now available.

Effective July 1, 2021, the brand-name drug: Azopt Susp 1% will be removed from the Kaiser Permanente Medicare Part D Drug List as generic alternative is now available.

Affected members who were prescribed these drugs prior to each effective date will be grandfathered, meaning members will continue to receive the removed product under their Part D benefit and continue to receive the product, except for members who have been converted to the generic alternatives.

# Provider E-News

## Provider Services Department



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The following table lists all products recently removed from the Medicare Part D Formulary.

Reason for change	Drug Name/Description	Date and Type of Change:	Alternate Drug  (Note: Over-the-counter (OTC) drugs are not covered under the Medicare Part D benefit)
Generic Available	LYRICA CR TB24 82.5 MG, 165 MG, 330 MG,	July 1, 2021  Brand drug to be replaced with generic	PREGABALIN ER TB24 82.5 MG, 165 MG, 330 MG
Generic Available	AZOPT SUSP 1 %	July 1, 2021  Brand drug to be replaced with generic	BRINZOLAMIDE SUSP 1 %
Removed from Drug List	GLUCAGON EMERGENCY KIT 1 MG (Eli Lilly and Company)	June 1, 2021  Removed from Drug List	GLUCAGON EMERGENCY KIT 1 MG (Amphastar Pharmaceuticals, Inc.)
Generic Available	NORTHERA CAPS 100 MG, 200 MG, 300 MG	June 1, 2021  Brand drug to be replaced with generic	DROXIDOPA CAPS 100 MG, 200 MG, 300 MG
Generic Available	VIVLODEX CAPS 5 MG, 10 MG	May 1, 2021  Brand drug to be replaced with generic	MELOXICAM CAPS 5MG, 10 MG
Generic Available	TRUVADA TABS 100-150 MG, 133-200 MG, 167-250 MG	May 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 100-150 MG, 133-200 MG, 167-250 MG
Removed from Drug List	LOTEPREDNOL ETABONATE GEL 0.5 %	May 1, 2021  Removed from Drug List	LOTEMAX GEL 0.5%



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Generic Available	ADVAIR DISKUS AEPB 100-50 MCG/DOSE, 250- 50 MCG/DOSE, 500-50 MCG/DOSE	May 1, 2021  Brand drug to be replaced with generic	WIXELA INHUB AEPB 100-50 MCG/DOSE, 250-50 MCG/DOSE, 500-50 MCG/DOSE
Generic Available	EMTRIVA CAPS 200MG	April 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE CAPS 200 MG
Generic Available	ATRIPLA TABS 600-200- 300MG	April 1, 2021  Brand drug to be replaced with generic	EFAVIRENZ-EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 600-200-300 MG
Generic Available	LIBRAX CAPS 5-2.5 MG	March 1, 2021  Brand drug to be replaced with generic	CHLORDIAZEPOXIDE-CLIDINIUM CAPS 5-2.5 MG
Generic Available	MONUROL PACK 3 GM	February 1, 2021  Brand drug to be replaced with generic	FOSFOMYCIN TROMETHAMINE PACK 3 GM
Generic Available	KERYDIN SOLN 5 %	February 1, 2021  Brand drug to be replaced with generic	TAVABOROLE SOLN 5 %
Generic Available	TIMOPTIC OCUDOSE SOLN 0.5 %	February 1, 2021  Brand drug to be replaced with generic	TIMOLOL MALEATE PF SOLN 0.5 %
Generic Available	TRUVADA TABS 200-300 MG	February 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 200-300 MG

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**Product Removal: Glucagon Emergency Kit 1 MG (by Eli Lilly); Northera Caps 100 MG, 200 MG, 300 MG**

Effective June 1, 2021, the brand-name drug Glucagon Emergency Kit (Eli Lilly and Co.) will be removed from our Drug List.

Effective June 1, 2021, the brand-name drug: Northera Caps 100 MG, 200 MG, 300 MG will be removed from the KP Medicare Part D Drug List as generic alternative is now available.

Affected members who were prescribed these drugs prior to each effective date will be grandfathered, meaning members will continue to receive the removed product under their Part D benefit and continue to receive the product, except for members who have been converted to the generic alternatives.

The following table lists all products recently removed from the Medicare Part D Formulary.

Reason for change	Drug Name/Description	Date and Type of Change:	Alternate Drug  (Note: Over-the-counter (OTC) drugs are not covered under the Medicare Part D benefit)
Removed from Drug List	GLUCAGON EMERGENCY KIT 1 MG (Eli Lilly and Company)	June 1, 2021  Removed from Drug List	GLUCAGON EMERGENCY KIT 1 MG (Amphastar Pharmaceuticals, Inc.)
Generic Available	NORTHERA CAPS 100 MG, 200 MG, 300 MG	June 1, 2021  Brand drug to be replaced with generic	DROXIDOPA CAPS 100 MG, 200 MG, 300 MG
Generic Available	VIVLODEX CAPS 5 MG, 10 MG	May 1, 2021  Brand drug to be replaced with generic	MELOXICAM CAPS 5MG, 10 MG
Generic Available	TRUVADA TABS 100-150 MG, 133-200 MG, 167-250 MG	May 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 100-150 MG, 133-200 MG, 167-250 MG
Removed from Drug List	LOTEPREDNOL ETABONATE GEL 0.5 %	May 1, 2021  Removed from Drug List	LOTEMAX GEL 0.5%

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## Provider Services Department



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Generic Available	ADVAIR DISKUS AEPB 100-50 MCG/DOSE, 250- 50 MCG/DOSE, 500-50 MCG/DOSE	May 1, 2021  Brand drug to be replaced with generic	WIXELA INHUB AEPB 100-50 MCG/DOSE, 250-50 MCG/DOSE, 500-50 MCG/DOSE
Generic Available	EMTRIVA CAPS 200MG	April 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE CAPS 200 MG
Generic Available	ATRIPLA TABS 600-200- 300MG	April 1, 2021  Brand drug to be replaced with generic	EFAVIRENZ-EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 600-200-300 MG
Generic Available	LIBRAX CAPS 5-2.5 MG	March 1, 2021  Brand drug to be replaced with generic	CHLORDIAZEPOXIDE-CLIDINIUM CAPS 5-2.5 MG
Generic Available	MONUROL PACK 3 GM	February 1, 2021  Brand drug to be replaced with generic	FOSFOMYCIN TROMETHAMINE PACK 3 GM
Generic Available	KERYDIN SOLN 5 %	February 1, 2021  Brand drug to be replaced with generic	TAVABOROLE SOLN 5 %
Generic Available	TIMOPTIC OCUDOSE SOLN 0.5 %	February 1, 2021  Brand drug to be replaced with generic	TIMOLOL MALEATE PF SOLN 0.5 %
Generic Available	TRUVADA TABS 200-300 MG	February 1, 2021  Brand drug to be replaced with generic	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARATE TABS 200-300 MG

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## Please remember to advise your Provider Services Consultant



### **Have you made any recent changes to your practice?**

Don't forget to let us know so we can update our [provider directory](#). On our [provider site](#) home page, click on Provider Support, and choose [Provider Demographic and/or Practice Changes](#). You will find several helpful links on that page to provide us with information.

On this page, you will be able to:

- Add new practitioners or term practitioners, including advanced registered nurse practitioners, physician assistants, and locum tenens
- Submit staff changes: in case we must adjust our records of clinic staff with Kaiser Permanente Electronic Medical Record (EMR) access.
- Submit demographic and business updates, including:
  - Clinic/services location updates
  - Close a clinic location
  - Remit/billing "Pay to" address updates
  - Tax ID update / Tax ID address update / 1099 address update

Thank you for helping us maintain a compliant and accurate provider directory.