

# Special Report: 2024 Neurology Drug & Device Approvals & Clearances

A quick reference for the drugs and devices for neurologic conditions that received approval or clearance notice from the Food and Drug Administration (FDA) last year

## ALZHEIMER DISEASE & DEMENTIA

In 2024, we saw the approval of Kisunla (donanemab-azbt; Eli Lilly and Company, Indianapolis, IN), a monoclonal antibody (mAb) administered as a once-monthly injection for intravenous (IV) use in people with early symptomatic Alzheimer disease (AD). Additionally, 510(k) clearances were granted to 3 software tools that assist in the clinical assessment of brain images: Brainsee (Darmiyan, San Francisco, CA), NeuroQuant v5.0 (Cortechs.ai, San Diego, CA), and Icobrain Aria (Icometrix, Boston, MA).

APPROVALS FOR ALZHEIMER DISEASE & DEMENTIA			
Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
BrainSee (Darmiyan, San Francisco, CA)	January 12, 2024	Prognostic tool to aid in the clinical assessment of how likely patients aged between 55 and 95 years who are diagnosed with amnesic mild cognitive impairment are to progress to clinical Alzheimer disease (AD)-dementia within 5 years of assessment.	Artificial intelligence software
Kisunla (donanemab-azbt; Eli Lilly and Company, Indianapolis, IN)	July 2, 2024	Kisunla is an amyloid beta-directed antibody indicated for the treatment of Alzheimer disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.	Injection for intravenous use
NeuroQuant v5.0 (Cortechs.ai, San Diego, CA)	August 22, 2024	Use for automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric measurements may be compared to reference percentile data.	Medical image management and processing system
Icobrain Aria (Icometrix, Boston, MA)	November 7, 2024	Use as a concurrent reading aid to help trained radiologists in the detection, assessment and characterization of amyloid-related imaging abnormalities (ARIA) from a set of brain MRI images.	Radiological computer-assisted detection and diagnosis software

## CHILD NEUROLOGY

In 2024, the FDA approved the first 2 drugs indicated for the treatment of adult and pediatric patients with Niemann-Pick disease type C (NPC). First, Miplyffa (arimoclomol; Zevra Therapeutics, Celebration, FL) was approved for use in combination with miglustat for the treatment of neurologic manifestations of NPC, administered as an oral capsule 3 times daily. Aqneursa (levacetylleucine; IntraBio, Austin, TX) was subsequently approved as the first ever stand-alone therapy for NPC, a suspension for oral administration or administration via gastrostomy tube up to 3 times daily, depending on patient body weight.

## APPROVALS FOR CHILD NEUROLOGY

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Miplyffa (arimoclomol; Zevra Therapeutics, Celebration, FL)	September 20, 2024	Miplyffa is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C in adult and pediatric patients aged 2 years and older.	Capsules for oral use in combination with miglustat
Aqneursa (levacetylleucine; IntraBio, Austin, TX)	September 25, 2024	Aqneursa is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C in adults and pediatric patients weighing $\geq 15$ kg.	Suspension for oral administration or administration via gastrostomy tube

## EPILEPSY &amp; SEIZURES

In 2024, the FDA approved Libervant (diazepam buccal film; Aquestive Therapeutics, Warren, NJ) for pediatric patients with epilepsy for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity. Libervant is a buccal film administered on the inside of the mouth on top of the surface of the cheek. Additionally, 510(k) clearances were granted to 2 EEG devices, ONE (Zeto, Santa Clara, CA) and BrainWatch (Natus, Middleton, WI), which both have applications in monitoring seizure activity.

## APPROVALS FOR EPILEPSY &amp; SEIZURES

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Libervant (diazepam buccal film; Aquestive Therapeutics, Warren, NJ)	April 26, 2024	Libervant is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy aged 2 to 5 years.	Buccal film applied on the inside of the mouth on top of the surface of the cheek
ONE (Zeto, Santa Clara, CA)	April 30, 2024	Use in a healthcare facility, home, and specific transport environments to acquire, transmit, display, and store EEG and auxiliary signals for adults and children, not including newborns.	Full-montage standard EEG
BrainWatch (Natus, Middleton, WI)	November 19, 2024	Record and store EEG signals and present these signals visually to assist trained medical staff in making neurological diagnoses in patients aged 2 years and older.	Reduced-montage standard EEG



## HEADACHE & PAIN

One device received 510(k) clearance for headache in 2024: Nerivio (Theranica, Bridgewater Township, NJ), a transcutaneous electrical stimulator for the treatment of acute migraine. Nerivio is a self-administered device for both acute and preventive treatment in the home setting.

### APPROVALS FOR HEADACHE & PAIN

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Nerivio (Theranica, Bridgewater Township, NJ)	October 8, 2024	Nerivio is indicated for acute and/or preventive treatment of migraine with or without aura in patients 8 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.	Distal transcutaneous electrical stimulator for treatment of acute migraine

## IMAGING & TESTING

There were 3 510(k) clearances in 2024 for devices that have indications for imaging and testing. The SmartFrame OR Stereotactic System (ClearPoint Neuro, Solana Beach, CA) is a stereotaxic instrument with applications in surgical procedures, whereas NeuroLF (Positrgo, Zurich, Switzerland) is an emission computed tomography system that can assist in the diagnosis and management of neurologic conditions. Smart Skin (X-trodes System M; X-trodes, Tel Aviv, Israel) is a physiological signal amplifier with utility for people with cardiovascular and sleep disorders.

### APPROVALS FOR IMAGING & TESTING

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
SmartFrame OR Stereotactic System (ClearPoint Neuro, Solana Beach, CA)	January 12, 2024	Provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction.	Neurological stereotaxic instrument
Smart Skin (X-trodes System M; X-trodes, Tel Aviv, Israel)	February 4, 2024	Prescription use only in the home or healthcare facility to acquire, record, transmit and display physiological signals from adult patients. The X-trodes System M acquires, records, transmits, and displays EEG, EOG, ECG, and/or EMG, and accelerometer and gyroscope signals. The X-trodes System M only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision, and reliability.	Physiological signal amplifier
NeuroLF (Positrgo, Zurich, Switzerland)	July 15, 2024	Use to detect and display the distribution of positron-emitting radionuclides within parts of the human body to assist in diagnosis, therapeutic planning, and therapeutic outcome assessment. The NeuroLF seat is intended to properly position the patient for PET imaging of the neck or head with the NeuroLF.	Emission computed tomography system

## MOVEMENT DISORDERS

In 2024, we saw the approval of Crexont (carbidopa and levodopa, Amneal Pharmaceuticals, Bridgewater, NJ), a novel formulation of carbidopa/levodopa for the treatment of Parkinson disease (PD). There also were 3 approvals for new indications or formulations for Ingrezza (valbenazine; Neurocrine Biosciences, San Diego, CA), Austedo (deutetrabenazine; Teva Neuroscience, Kansas City, MO), and Brineura (cerliponase alfa; BioMarin Pharmaceuticals, San Rafael, CA). Additionally, the Percept RC DBS system (Medtronic, Minneapolis, MN) received 510(k) clearance for the suppression of tremor using thalamic stimulation.

## APPROVALS FOR MOVEMENT DISORDERS

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Percept RC DBS system (Medtronic, Minneapolis, MN)	January 8, 2024	Unilateral thalamic stimulation for the suppression of tremor in the upper extremity in patients who are diagnosed with essential tremor (ET) or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.	Implanted thalamic stimulator device
Ingrezza Sprinkle (valbenazine; Neurocrine Biosciences, San Diego, CA)	April 30, 2024	Ingrezza Sprinkle is indicated for the treatment of adults with: <ul style="list-style-type: none"> <li>• Tardive dyskinesia (TD)</li> <li>• Chorea associated with Huntington disease (HD)</li> </ul>	Capsule containing sprinkle for oral administration with or without food
Austedo XR (deutetrabenazine; Teva Neuroscience, Kansas City, MO)	May 29, 2024	Austedo XR is indicated in adults for the treatment of: <ul style="list-style-type: none"> <li>• Chorea associated with Huntington disease (HD)</li> <li>• Tardive dyskinesia (TD)</li> </ul>	Extended-release tablets for oral use
Brineura (cerliponase alfa; BioMarin Pharmaceuticals, San Rafael, CA)	July 24, 2024	Brineura is indicated to slow the loss of ambulation in symptomatic pediatric patients aged 3 years and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.	Injection for intraventricular use
Crexont (carbidopa and levodopa; Amneal Pharmaceuticals, Bridgewater, NJ)	August 7, 2024	Crexont is indicated for the treatment of Parkinson disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide (CO) intoxication or manganese intoxication in adults.	Extended-release capsules for oral use
Vyalev (foscarbidopa and foslevodopa; AbbVie, North Chicago, IL)	October 17, 2024	Vyalev is indicated for the treatment of motor fluctuations in adults with advanced Parkinson disease (PD).	Injection for subcutaneous administration via the Vyafuser pump (provided separately)
Kebilidi (eladocagene exuparvovec-tneq; PTC Therapeutics, Warren, NJ)	November 13, 2024	Kebilidi is indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.	Suspension for intraputamenal infusion



## MS & IMMUNE DISORDERS

Ocrevus Zunovo (ocrelizumab & hyaluronidase-ocsq; Genentech, South San Francisco, CA), a novel subcutaneous formulation of ocrelizumab, received FDA approval in 2024 for the treatment of people with multiple sclerosis (MS). Additionally, the FDA approved new indications for HyQvia (Immune Globulin Infusion 10% [Human] with Recombinant Human Hyaluronidase; Takeda, Cambridge, MA), Gammagard Liquid (Immune Globulin Infusion [human] 10% solution; Takeda, Cambridge, MA), Ultomiris (ravulizumab-cwvz; Alexion, Boston, MA), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc; Argenx, Amsterdam, Netherlands).

### APPROVALS FOR MS & IMMUNE DISORDERS

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
HyQvia (Immune Globulin Infusion 10% [Human] with Recombinant Human Hyaluronidase; Takeda, Cambridge, MA)	January 12, 2024	Hyqvia is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.	Solution for subcutaneous administration
Gammagard Liquid (Immune Globulin Infusion [human] 10% solution; Takeda, Cambridge, MA)	January 29, 2024	Gammagard Liquid is indicated as a therapy to improve neuromuscular disability and impairment in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).	Solution for intravenous or subcutaneous administration
Ultomiris (ravulizumab-cwvz; Alexion, Boston, MA)	March 25, 2024	Ultomiris is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 antibody positive (AQP4+).	Injection for intravenous use
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc; Argenx, Amsterdam, Netherlands)	June 21, 2024	Vyvgart Hytrulo is indicated for the treatment of adult patients with: <ul style="list-style-type: none"> <li>• Generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive</li> <li>• Chronic inflammatory demyelinating polyneuropathy (CIDP)</li> </ul>	Injection for subcutaneous use
Ocrevus Zunovo (ocrelizumab & hyaluronidase-ocsq; Genentech, South San Francisco, CA)	September 17, 2024	Ocrevus Zunovo is indicated for the treatment of: <ul style="list-style-type: none"> <li>• Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease, in adults</li> <li>• Primary progressive MS in adults</li> </ul>	Injection for subcutaneous use

**NEUROMUSCULAR DISORDERS**

For neuromuscular disorders, 3 new drugs received FDA approvals, including generic deflazacort (Tris Pharma, Monmouth Junction, NJ), Lenmeldy (atidarsagene autotemcel; Orchard Therapeutics, London, UK), and Duvyzat (givinostat; italfarmaco SpA, Milan, Italy). Additionally, the FDA broadened the indication for Elevidys (delandistrogene moxeparvovec-rokl; Sarepta Therapeutics, Cambridge, MA) to treat children aged  $\geq 4$  years with Duchenne muscular dystrophy (DMD).

**APPROVALS FOR NEUROMUSCULAR DISORDERS**

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Lenmeldy (atidarsagene autotemcel, Orchard Therapeutics, London, UK)	March 18, 2024	Lenmeldy is indicated for the treatment of children with pre-symptomatic late infantile, presymptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy (MLD).	Suspension for intravenous infusion
Duvyzat (givinostat; Italfarmaco SpA, Milan, Italy)	March 21, 2024	Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 6 years and older.	Suspension for oral administration with food
Generic deflazacort (Tris Pharma, Monmouth Junction, NJ)	April 25, 2024	Deflazacort is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 5 years and older.	Suspension for oral administration
Elevidys (delandistrogene moxeparvovec-rokl; Sarepta Therapeutics, Cambridge, MA)	June 20, 2024	Elevidys is indicated in individuals aged at least 4 years: <ul style="list-style-type: none"> <li>For the treatment of Duchenne muscular dystrophy (DMD) in patients who are ambulatory and have a confirmed mutation in the DMD gene</li> <li>For the treatment of DMD in patients who are nonambulatory and have a confirmed mutation in the DMD gene</li> </ul>	Suspension for intravenous infusion

**NEURO-ONCOLOGY**

There was one approval in 2024 for a drug in neuro-oncology. Voranigo (vorasidenib; Servier, Boston, MA), an oral tablet, received approval for adult and pediatric patients with specific forms of Grade 2 astrocytoma or oligodendroglioma. Treatment with Voranigo is indicated only after surgery.

**APPROVALS FOR NEURO-ONCOLOGY**

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Voranigo (vorasidenib; Servier, Boston, MA)	August 6, 2024	Voranigo is indicated for the treatment of adult and pediatric patients aged 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.	Tablets for oral use



## SLEEP

In 2024, 2 oral tablets, Wakix (pitolisant; Harmony Biosciences, Plymouth Meeting, PA) and Lumryz (sodium oxybate; Avadel Pharmaceuticals, Dublin, Ireland) received FDA approvals for expanded indications in the treatment of excessive daytime sleepiness (EDS), cataplexy, and narcolepsy. Additionally, the SANSA (Huxley Medical, Atlanta, GA) breathing monitor device and the Happy Ring Health Monitoring System (Happy Health, Austin, TX) cardiac monitor device received 510(k) clearances for use in sleep.

### APPROVALS FOR SLEEP

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Wakix (pitolisant; Harmony Biosciences, Plymouth Meeting, PA)	June 24, 2024	Wakix is indicated for the: <ul style="list-style-type: none"> <li>• Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy</li> <li>• Treatment of excessive daytime sleepiness (EDS) in pediatric patients aged 6 years and older with narcolepsy</li> </ul>	Tablets for oral use
SANSA (Huxley Medical, Atlanta, GA)	July 15, 2024	Use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and home use setting under the direction of a healthcare professional.	Breathing frequency monitor patch worn on the chest
Happy Ring Health Monitoring System (Happy Health, Austin, TX)	September 24, 2024	Use to remotely monitor physiologic parameters of patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. The device is intended for use on individuals who are aged 22 years and older.	Cardiac monitor including cardi tachometer and rate alarm
Lumryz (sodium oxybate; Avadel Pharmaceuticals, Dublin, Ireland)	October 27, 2024	Lumryz is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients aged 7 years and older with narcolepsy.	Extended-release oral suspension

**STROKE**

In stroke, there were 4 new 510(k) device clearances in 2024. Viz ICH Plus (Viz.ai, San Francisco, CA), Cina-ASPECTS (Avicenna.AI, La Ciotat, France), and AngioFlow (RapidAI, San Mateo, CA) were approved for automated or computer-assisted analysis of brain images, while Neuroblade System (Clearmind Biomedical, San Jose, CA) was cleared as an endoscope for use during surgery.

**APPROVALS FOR STROKE**

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
Viz ICH Plus (Viz.ai, San Francisco, CA)	February 5, 2024	Automatic labeling, visualization, and quantification of segmentable brain structures from a set of non-contrast CT (NCCT) head scans. The software is intended to automate the current manual process of identifying, labeling, and quantifying the volume of segmentable brain structures identified on NCCT images. Viz HDS provides volumes from NCCT scans acquired at a single time point. The Viz HDS software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift. The device output should be reviewed along with patient's original images by a physician.	Automated radiological image processing software
Cina-ASPECTS (Avicenna.AI, La Ciotat, France)	March 15, 2024	Assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data.	Computer-assisted diagnostic software for lesions suspicious for cancer
AngioFlow (RapidAI, San Mateo, CA)	May 6, 2024	Qualitative perfusion imaging analysis to provide maps that assess ischemic change in brain regions with reduced cerebral blood flow.	Artificial intelligence module
Neuroblade System (Clearmind Biomedical, San Jose, CA)	August 26, 2024	Use for the illumination and visualization of intracranial tissue and fluids, controlled aspiration of tissue and/or fluid, powered cutting of soft tissue, and coagulation of tissue under direct visualization during surgery of the ventricular system or cerebrum.	Neurological endoscope

**TBI**

In 2024, the i-STAT TBI Cartridge (Abbott, Chicago, IL) blood test device received 510(k) clearance for use in evaluating mild traumatic brain injury (mTBI).

**APPROVALS FOR TBI**

Drug/Device (Generic Name; Manufacturer)	Approval/Clearance	Indication	Available as
i-STAT TBI Cartridge (Abbott, Chicago, IL)	March 27, 2024	Quantitative measurement of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in whole blood and a semi-quantitative interpretation of test results derived from these measurements, using the i-STAT Alinity instrument to aid in the evaluation of mild traumatic brain injury (mTBI).	Brain trauma assessment test