

### Editorial

Obesity is a major medical problem globally. It is not only stigmatized but has negative effects on health as well. FDA has approved a new medicine (*Inj. Zepbound*) for chronic weight management in adults. This is recommended for people with a BMI over 30kg/m<sup>2</sup> and have at least one weight-related condition (such as high blood pressure, type 2 diabetes or high cholesterol). It is to be used in addition to a reduced calorie diet and increased physical activity. The FDA has also approved the first oral therapy, *Osgiveo*, for adults with progressing desmoid tumours.

Amongst individuals with early Alzheimer's disease, the use of *Gantenerumab* in two phase-3 trials was found to lead to a lower amyloid plaque burden than placebo at 116 weeks but was not associated with slower clinical decline. In another phase-3 double-blind randomized study, the benefit-risk ratio of once-daily *Multimatrix Mesalamine* in paediatric patients was found to be favourable and comparable with that reported in adults with mild-to-moderate UC.

Several useful innovative devices are being developed and used for various medical conditions. The *LapBox* tissue containment system (Ark Surgical), is one of such devices which enables minimally invasive hysterectomies with manual morcellation for improved patient outcomes and lowered risk of cancer cell spread.

NICE has published new guidelines for 'percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism', 'percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis', 'transient loss of consciousness ('blackouts') in over 16s', 'suspected acute respiratory infection in over 16s: assessment at first presentation and initial management', and 'biodegradable subacromial spacer insertion for rotator cuff tears'.

The JCI has published a multicenter study of the factors associated with falls in elderly hospitalized patients and reported that the patients who experience a fall meeting the CMS-HAC fall definition are significantly more likely to have a prior history of falling, dementia, and a higher ACB score. Results from this study may inform future quality improvement work aimed at reducing injurious falls.

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## I. Drugs

### **FDA Approves First Therapy for Rare Type of Non-Cancerous Tumors**

Source: The FDA, November 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-interchangeable-biosimilar-multiple-inflammatory-diseases>

Ogsiveo tablets for adult patients with progressing desmoid tumors who require systemic treatment. Ogsiveo is the first drug to be approved for the treatment of patients with desmoid tumors, a rare subtype of soft tissue sarcomas.

### **FDA Approves First Treatment for Patients with Rare Inherited Blood Clotting Disorder**

Source: The FDA, November 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-rare-inherited-blood-clotting-disorder>

Adzynma, the first recombinant (genetically engineered) protein product indicated for prophylactic (preventive) or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP), a rare and life-threatening blood clotting disorder.

### **FDA Clears First COVID-19 Home Antigen Test**

Source: The FDA, November 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-clears-first-covid-19-home-antigen-test>

The Flowflex COVID-19 Antigen Home Test is a visually-read test cleared for OTC home use by symptomatic individuals within six days of symptom onset. It is cleared for individuals aged 14 years or older testing themselves, or adults testing individuals aged two years or older.

### **FDA Approves New Medication for Chronic Weight Management**

Source: The FDA, November 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management>

Zepbound injection for chronic weight management in adults with obesity (body mass index of 30 kilograms per square meter (kg/ m<sup>2</sup>) or greater) or overweight (body mass index of 27 kg/m<sup>2</sup> or greater) with at least one weight-related condition (such as high blood pressure, type 2 diabetes or high cholesterol) for use, in addition to a reduced calorie diet and increased physical activity.

## II. Clinical Research

### **Two Phase 3 Trials of Gantenerumab in Early Alzheimer's Disease**

Source: The NEJM, November 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2304430>

Among persons with early Alzheimer's disease, the use of gantenerumab led to a lower amyloid plaque burden than placebo at 116 weeks but was not associated with slower clinical decline.

### **Safety and efficacy of multimatrix mesalamine in paediatric patients with mild-to-moderate ulcerative colitis: a phase 3, randomised, double-blind study**

Source: The Lancet, November 2023

Link: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(23\)00409-1/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(23)00409-1/fulltext)

Benefit-risk ratio of once-daily multimatrix mesalamine in paediatric patients was favourable and comparable with that reported in adults with mild-to-moderate UC.

## **III. Devices**

### **Ark Surgical Performs First Hysterectomies in the USA with its FDA-Cleared LapBox for Manual Morcellation**

Source: The FDA, November 2023

Link: [https://www.medgadget.com/2023/11/ark-surgical-performs-first-hysterectomies-in-the-usa-with-its-fda-cleared-lapbox-for-manual-morcellation.html#google\\_vignette](https://www.medgadget.com/2023/11/ark-surgical-performs-first-hysterectomies-in-the-usa-with-its-fda-cleared-lapbox-for-manual-morcellation.html#google_vignette)

The LapBox tissue containment system enables minimally invasive hysterectomies with manual morcellation for improved patient outcomes and lowered risk of cancer cell spread.

### **FDA Grants Marketing Authorization of First Test for Chlamydia and Gonorrhea with at-home Sample Collection**

Source: The FDA, November 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-test-chlamydia-and-gonorrhea-home-sample-collection>

LetsGetChecked for the Simple 2 Test is available over-the-counter (OTC) and is intended for use in adult patients ages 18 years and older. It is the first FDA-authorized test with at-home sample collection for any sexually-transmitted disease other than HIV.

### **Flow transcranial direct current stimulation for treating depression**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/advice/mib324>

Flow (Flow Neuroscience) consists of a transcranial direct current stimulation (tDCS) headset and a behavioural therapy app. It is intended for treating adults diagnosed with major depressive disorder at home. tDCS involves non-invasive electrical stimulation of the brain by applying a weak direct current to the forehead. Flow uses tDCS to stimulate brain activity in the dorsolateral prefrontal cortex (DLPFC) region to help reduce depression. The Flow headset delivers an electrical current (2 mA) to the DLPFC through electrodes placed on the forehead, directly targeting areas of the brain involved in depression. The Flow headset is portable and wireless. The device can be controlled using the Flow app (using a Bluetooth connection), which is compatible with iOS and Android.

## **IV. Treatment Guidelines**

### **Percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/guidance/ipg778>

The first-line treatment for PE is systemic or oral anticoagulants. For high- or intermediate-risk PE with haemodynamic compromise, systemic thrombolysis may be used or, rarely, open surgical embolectomy. Catheter-directed therapies may also be used, including catheter-directed thrombolysis and percutaneous

thrombectomy. Catheter-directed therapies are usually used if someone has a high-risk PE and they cannot have surgery, or when systemic thrombolysis is contraindicated or has failed.

#### **Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/guidance/ipg777>

Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis. This involves using a wire mesh tube called a stent to widen the narrowed carotid artery.

#### **Transient loss of consciousness ('blackouts') in over 16s**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/guidance/cg109>

This guideline covers assessment, diagnosis and referral for people over 16 who have had a transient loss of consciousness. It aims to improve care for people with TLoC by specifying the most effective assessments and recommending when to refer to a specialist.

#### **Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/guidance/ng237>

This guideline covers assessment of people aged 16 and over with symptoms and signs of acute respiratory infection (bacterial or viral) at first remote or in-person contact with NHS services. It also covers the initial management of any infections. It aims to support healthcare practitioners in making sure that people's treatment follows the best care pathway.

#### **Biodegradable subacromial spacer insertion for rotator cuff tears**

Source: The NICE, November 2023

Link: <https://www.nice.org.uk/guidance/ipg775>

Biodegradable subacromial spacer insertion for rotator cuff tears. This involves inserting a balloon-shaped device between the top of the shoulder blade and the upper arm bone to reduce pain and improve shoulder function.

## **V. Healthcare Administration**

#### **Factors Associated with Acute Injurious Falls in Elderly Hospitalized Patients: A Multicenter Descriptive Study**

Source: The JCI, November 2023

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(23\)00157-5/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(23)00157-5/fulltext)

Patients who experience a fall meeting the CMS-HAC fall definition are significantly more likely to have a prior history of falling, dementia, and a higher ACB score. Results from this study may inform future quality improvement work aimed at reducing injurious falls.