Health Technology Briefing
March 2026

Botulinum toxin type A for preventing episodic migraine

Company/Developer	Ipsen Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 39399	NICE ID: Not available	UKPS ID: 675333

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

Botulinum toxin type A is being developed to prevent episodic migraine. Migraine is a debilitating headache disorder. Symptoms may include nausea (feeling sick), vomiting (being sick), and increased sensitivity to light, sound or smells. Migraine may be with or without aura (symptoms visual disturbances, problems with speech, numbness or pins and needles). The headaches of episodic migraine (with or without aura) occur on fewer than 15 days per month. Episodic migraine may develop into long-term (chronic) migraine (headache on 15 or more days a month). It is not known what causes migraine. Some conditions such as depression and anxiety, and triggers such as stress and tiredness, can cause migraines in some people. There is no cure for migraine, and management of episodic migraine is focused on preventive treatment to reduce headache frequency, duration, and severity.

Botulinum toxin type A is given as injections into various muscles across the head, neck, face and shoulders. It works by blocking signals from the nerve to the muscle that has been injected; the nerve is unable to tell the muscle to move, which means that the muscle is then able to relax. This helps to stop migraine headaches developing. If approved, botulinum toxin type A will offer an addition option for the prevention of episodic migraine.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.
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Proposed Indication

Prevention of episodic migraine in adults.[1]

Technology

Description

Botulinum toxin type A (Dysport)[1] is a purified form of a neurotoxin (a toxin that affects nerves), which is derived from Clostridium bacteria.[2,3] Botulinum toxin type A works by blocking signals from the nerve to the muscle that has been injected; the nerve is unable to tell the muscle to move, which means that the muscle is then able to relax. This helps to stop migraine headaches developing.[3]

Botulinum toxin type A is in clinical development for the prevention of episodic migraine. In the phase III trial (NCT06047457), botulinum toxin type A is administered as an intramuscular injection every 12 weeks during a period of 36 weeks, with a total of 4 injections.[1]

Key Innovation

There is no cure for migraine.[4] Episodic migraine is a debilitating condition that requires the use of preventive management to reduce the frequency, duration, or severity of attacks.[5] However, many patients do not like taking daily oral medication, which is either poorly tolerated or ineffective.[6] The impact of migraine can affect mental health, cause suicidal thoughts, lower participation in social occasions and impact work.[7] It also costs the UK up to £9 billion a year in lost workdays and presenteeism.[8]

Botulinum toxin type A is administered as an intramuscular injection every 12 weeks.[1] Advantages of administration by intramuscular injection include rapid absorption and onset of action (compared to oral and subcutaneous).[9] If licensed, botulinum toxin type A would offer an additional option for the prevention of episodic migraine.

Regulatory & Development Status

Botulinum toxin type A currently has Marketing Authorisation in the EU/UK for:[10,11]

- Symptomatic treatment of focal spasticity of:
  - Upper limbs in adults
  - Lower limbs in adults affecting the ankle joint
  - Dynamic equinus foot deformity in ambulant paediatric cerebral palsy patients, two years of age or older
  - Upper limbs in paediatric cerebral palsy patients, two years of age or older.
- The management of urinary incontinence in adults with neurogenic detrusor overactivity due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are regularly performing clean intermittent catheterisation.
- Symptomatic treatment in adults of:
  - Spasmodic torticollis
  - Blepharospasm
  - Hemifacial spasm
  - Severe primary hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics.
- Prophylaxis in headaches in chronic migraine
- Temporary improvement of moderate to severe upper facial lines in adults under 65 years
- Chronic sialorrhoea due to neurological disorders

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Botulinum toxin type A is in phase III/II clinical development for:[12]

- Spasticity
- Chronic migraine
- Facial lines

Patient Group

Disease Area and Clinical Need

Migraine is defined as at least 5 lifetime attacks of headache lasting 4 to 72 hours with at least two of the following pain characteristics: unilateral, pulsating, moderate or severe intensity; and the headache is associated with at least one of: nausea/vomiting, photophobia, phonophobia; and no more likely cause of headache identified. Migraine may or may not be preceded by an aura. Aura symptoms, if present, are fully reversible and typically consist of visual symptoms such as zigzag lines and/or scotoma; sensory symptoms such as unilateral pins and needles or numbness; speech and/or language symptoms such as dysphasia. Aura symptoms typically last 5-60 minutes and are followed by headache within 60 minutes. Two or more aura symptoms may follow in succession.[13] The headaches of episodic migraine (with or without aura) occur on fewer than 15 days per month.[14] Around 2.5 out of 100 people with episodic migraine will develop chronic migraine (characterised by 15 or more headache days per month) each year.[15,16] It is not known what causes migraine.[17] There are a number of medical conditions that can increase a person's tendency to have migraine, including: depression; anxiety; other pain conditions such as fibromyalgia; sleep apnoea; postural orthostatic tachycardia syndrome.[15]

Around one in seven people in the UK live with migraine.[8] In England (2024-25), there were 47,536 finished consultant episodes (FCEs) and 39,207 finished admission episodes for migraine (ICD-10 code G43), which resulted in 13,808 FCE day cases and 34,995 FCE bed days.[18]

Recommended Treatment Options

NICE recommends the following options for preventing migraine:

- Atogepant for preventing migraine in adults who have at least 4 migraine days per month, only if at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns.[19]
- Rimegepant for preventing episodic migraine in adults who have at least 4 and fewer than 15 migraine attacks per month, only if at least 3 preventative medicines have not worked, or are not tolerated or are unsuitable because of safety concerns.[20]
- Eptinezumab for preventing migraine in adults, only if they have 4 or more migraine days a month, and at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns.[21]
- Fremanezumab for preventing migraine in adults, only if they have 4 or more migraine days a month, and at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns.[22]
- Erenumab for preventing migraine in adults, only if they have 4 or more migraine days a month, at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns, and the 140 mg dose of erenumab is used.[23]
- Galcanezumab for preventing migraine in adults, only if they have 4 or more migraine days a month, and at least 3 preventive medicines have not worked, or are not tolerated or are unsuitable because of safety concerns.[24]

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For each of these options, NICE recommends stopping after 12 weeks of treatment if in episodic migraine (fewer than 15 headache days a month) the frequency does not reduce by at least 50%.

Clinical Trial Information

Trial	**E-BEOND;** NCT06047457; 2023-504839-40-00; A Phase III, Randomised, Double-blind, Placebo-controlled, Multicenter, Parallel-group Study With Extension Phase to Evaluate the Efficacy and Safety of Dysport® for the Prevention of Episodic Migraine in Adult Participants **Phase III –** Active, not recruiting **Location(s):** Five EU countries, USA, Canada and Georgia **Primary completion date (estimated):** June 2026
Trial Design	Randomised, parallel assignment, double blinded
Population	N=751; aged 18 years and older; diagnosis of chronic migraine for more than 12 months; migraine onset occurred <50 years of age
Intervention(s)	Botulinum toxin type A (intramuscular)
Comparator(s)	Placebo (intramuscular)
Outcome(s)	Primary outcome: Change from baseline in monthly migraine days [Time frame: every 4 weeks from week 4 (weeks 1-4) to week 24 (weeks 21-24) See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Botulinum toxin type A is already marketed in the UK; 300 unit powder for solution for injection vials costs £92.40 NHS indicative price.[25]

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Atogepant for preventing migraine (TA973). May 2024.
- NICE technology appraisal. Rimegepant for preventing migraine (TA906). July 2023.
- NICE technology appraisal. Eptinezumab for preventing migraine (TA871). March 2023.
- NICE technology appraisal. Fremanezumab for preventing migraine (TA764). February 2022.
- NICE technology appraisal. Erenumab for preventing migraine (TA682). March 2021.
- NICE technology appraisal. Galcanezumab for preventing migraine (TA659). November 2020.
- NICE clinical guideline. Headaches in over 12s: diagnosis and management (CG150). June 2025.
- NICE quality standard. Headaches in over 12s (QS42). August 2013.
- NICE HealthTech guidance. Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine (HTG643). October 2022.
- NICE HealthTech guidance. Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (HTG408). March 2016.

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- NICE HealthTech guidance. Transcranial magnetic stimulation for treating and preventing migraine (HTG330). January 2014.
- NICE HealthTech guidance. Percutaneous closure of patent foramen ovale for recurrent migraine (HTG242). December 2010.

NHS England (Policy/Commissioning) Guidance

- NHS England. NHS Standard Contract for Specialised Pain. D08/S/a.
- NHS England. NHS Standard Contract for Neurosurgery. D03/S/a.
- NHS England. Clinical Commissioning Policy: Occipital Nerve Stimulation for Adults with Intractable Chronic Migraines and Medically Refractory Chronic Cluster Headaches. D08/P/c. July 2015.

Other Guidance

- Buckinghamshire, Oxfordshire and Berkshire West Integrated Care System. Migraine: Acute Therapy Guidelines (Adult). 2024.[26]
- Scottish Intercollegiate Guidelines Network. Pharmacological management of migraine. 2023.[27]
- British Association for the Study of Headache. National Headache Management System for Adults. 2019.[28]

Additional Information

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