

PRESS RELEASE

For UK consumer, medical and trade media

NICE recommends AbbVie's HUMIRA® (adalimumab) for treatment of non-infectious uveitis

- *NICE publishes guidance recommending AbbVie's HUMIRA® (adalimumab) as an option for treating eligible adults with certain types of non-infectious uveitis who have had an inadequate response to corticosteroids¹*
- *Non-infectious uveitis can lead to reduced vision or vision loss and is the third-leading cause of preventable blindness worldwide^{2,3}*
- *Adalimumab is the first and only biologic medicine licensed for adult patients with certain types of non-infectious uveitis*

MAIDENHEAD, UK, 26 July 2017 – AbbVie, a global biopharmaceutical company, today announced that the National Institute for Health and Care Excellence (NICE) has recommended HUMIRA® (adalimumab) as a clinically and cost effective treatment option for eligible adults with certain types of non-infectious uveitis who have had an inadequate response to corticosteroids¹.

Uveitis is an uncommon group of inflammatory eye conditions which can be caused either by infection or abnormal activation of the immune system in the uvea, the middle part of the eye^{4,5}. Non-infectious uveitis can lead to reduced vision or vision loss and is the third-leading cause of preventable blindness worldwide^{2,3}. It can affect both children and adults and is more common in people with an existing inflammatory or autoimmune condition⁵.

This NICE Technology Appraisal Guidance (TAG), which also provides recommendations on the use of dexamethasone, follows the publication of the 'Interim Clinical Commissioning Policy Statement: Adalimumab for Severe Refractory Uveitis' in March 2017⁶. It means that, for eligible patients, routine treatment is not limited to steroids and/or immunosuppressants. Treatment with steroids can be associated with a number of complications, therefore patients who have had an inadequate response to or who are intolerant to steroids and/or immunosuppressants may require another treatment option to control the inflammation in the eye^{5,7}. Adalimumab is the first and only biologic medicine licensed for adult patients with certain types of non-infectious uveitis (intermediate, posterior and pan-uveitis).

Annie Folkard, Co-Founder, Birdshot Uveitis Society said, "We are delighted that there is now another treatment option for those adults with severe uveitis who have not responded to other forms of treatment and who are at greatest risk of going blind. The effects of uveitis can be

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devastating. Not only can it make everyday tasks very difficult, but uncontrolled uveitis can also lead to irreversible deterioration of vision and ultimately blindness.”

Jessica Hall, RNIB Eye Health Policy Officer, said: “We very much welcome NICE’s recommendations as we finally have a routinely available treatment option, which has been shown to be safe and effective for those adults most at risk of sight loss.”

Mr Fahd Quhill, Consultant Ophthalmologist, Royal Hallamshire Hospital said, “Uveitis can be difficult to diagnose and treat, but due to its potentially life-long impact and the risk of complications it’s essential that the condition is treated effectively and inflammation is controlled. This new NICE guidance represents significant progress for those uveitis patients most at risk of going blind.”

This NICE TAG recommends adalimumab as an option for treating non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids, only if there is: active disease; inadequate response or intolerance to immunosuppressants; systemic disease or both eyes are affected; and worsening vision with a high risk of blindness¹.

When NICE recommends a treatment ‘as an option’, the NHS is required to comply with the recommendations and make it available for eligible patients in England and Wales within 3 months of the guidance being published¹.

The NICE TAG recommendation for adalimumab is based on efficacy and safety data from two randomised controlled trials, VISUAL-I and VISUAL-II. The studies demonstrated that adult patients with either active or controlled non-infectious intermediate, posterior and panuveitis treated with adalimumab had a significantly lower risk for uveitic flare or decrease in visual acuity, compared to placebo^{8,9}.

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Notes to editors

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world’s most complex and critical conditions. The company’s mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.co.uk.

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About adalimumab

For further information, please see the Summary of Product Characteristics:

<http://www.medicines.org.uk/emc>

About RNIB

Every 15 minutes, someone in the UK begins to lose their sight. We are the Royal National Institute of Blind People (RNIB) and we're here for everyone affected by sight loss - that's almost 2 million people in the UK. If you, or someone you know, has a sight problem, RNIB can help. Call the RNIB Helpline on 0303 123 9999 or visit www.rnib.org.uk

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1 National Institute for Health and Care Excellence. Adalimumab and dexamethasone for treating non-infectious uveitis Technology appraisal guidance [TA460]. July 2017. Available at: www.nice.org.uk/guidance/ta460 [Last accessed: July 2017].

2 Durrani OM, et al. Degree, duration, and causes of visual loss in uveitis. *British Journal of Ophthalmology* 2004;88:1159-1162.

3 Siddique SS, et al. Glaucoma and Uveitis. *Survey of Ophthalmology* 2013;58(1-10).

4 Jabs DA, et al. Standardization of Uveitis Nomenclature for Reporting Clinical Data. Results of the First International Workshop. *American Journal of Ophthalmology* 2005;140(3):509-516.

5 Guly CM and Forrester JV. Investigation and Management of Uveitis. *BMJ* 2010;341:821-826.

6 NHS England, Specialised Services Clinical Reference Group for Specialised Ear and Ophthalmology CRG, 'Interim Clinical Commissioning Policy Statement: Adalimumab with Severe Refractory Uveitis'. Available at: <https://www.england.nhs.uk/wp-content/uploads/2017/03/clin-com-pol-statement-170010ps.pdf>. [Last accessed: July 2017].

7 McCluskey PJ, et al. Management of Chronic Uveitis. *BMJ* 2000;320:555-558.

8 Jaffe GJ, et al. Adalimumab in Patients with Active Noninfectious Uveitis. *N Engl J Med* 2016;375(10):932-43.

9 Nguyen QD, et al. Adalimumab for prevention of uveitic flare in patients with inactive non-infectious uveitis controlled by corticosteroids (VISUAL II): a multicentre, double-masked, randomised, placebo-controlled phase 3 trial. *The Lancet* 2016;388:1183-1192.

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