NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Peramivir for treating acute, uncomplicated influenza

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of peramivir within its marketing authorisation for treating acute, uncomplicated influenza.

Background

Influenza is an acute respiratory illness caused by infection with influenza A and B viruses. It causes significant morbidity and increased mortality. Typical symptoms for uncomplicated influenza are cough, malaise, fever, chills, headache, nasal congestion, sore throat and aching muscles. However, symptoms can range from asymptomatic infection through respiratory illness (particularly bronchitis and pneumonia) to multi-system complications affecting the heart, lungs, brain, liver, kidneys and muscles. Influenza infection is usually self-limiting and lasts for 3–4 days, with some symptoms persisting for 1–2 weeks.

Older people, infants, people who might be immunosuppressed and people with chronic illnesses are more at risk of severe influenza, complications and hospitalisation associated with influenza. People living or working in residential care are at greater risk of infection. Influenza occurs in a seasonal pattern with outbreaks in the winter months, typically between December and March, however the overall burden is difficult to measure because many people do not access healthcare, and virological confirmation is very rarely performed[i]. In 2014, the peak weekly rate of GP consultations in England and Wales for influenza-like illness was 28.3 per 100,000[ii,iii]. The average annual number of deaths attributable to influenza in England is estimated to range from 4 deaths per year to 14,000 deaths per year, with an average of around 8,000 deaths per year[iv].

The treatment of influenza is mainly supportive, consisting of alleviation of symptoms and managing complications that may arise. NICE technology appraisal 168 recommends oseltamivir and zanamivir for the treatment of influenza in adults and children if: national surveillance schemes indicate that influenza virus A or B is circulating; the person is in an 'at-risk' group, and; the person has a 'flu-like illness' and can start treatment within 48 hours (or within 36 hours for zanamivir treatment in children) of the first sign of symptoms.

The technology

Peramivir (Rapivab, BioCryst Pharmaceuticals) is a neuraminidase inhibitor that is active against influenza A and B viruses. It prevents viral release from

infected cells and subsequent infection of adjacent cells. It is administered intravenously.

Peramivir does not currently have a marketing authorisation in the UK for treating acute, uncomplicated influenza. It has been studied in clinical trials compared with placebo and oseltamivir for treating adults with acute, uncomplicated influenza.

Intervention(s)	Peramivir
Population(s)	Adults with acute, uncomplicated influenza
Comparators	• best supportive care 'At-risk' groups: • oseltamivir • zanamivir
Outcomes	The outcome measures to be considered include: • length of influenza illness • time to return to normal activities • incidence of influenza-related complications • incidence of hospitalisations • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	If the evidence allows the following subgroups will be considered: • risk of infection • severity of disease • timing of the onset of the intervention from contact • viral resistance • extent of influenza circulating in the community Guidance will only be issued in accordance with the marketing authorisation Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: 'Amantadine, oseltamivir and zanamivir for the treatment of influenza' (2009). NICE technology appraisal TA168. Guidance on static list. 'Oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza' (2008). NICE Technology Appraisal 158. Guidance on static list.
Related National Policy	Department of Health, 'NHS Outcomes Framework 2015-2016', Dec 2014. Domains 1-5. NHS England 'Manual for prescribed specialised services 2013/14', 2014. Chapter 130.

Questions for consultation

How many people with uncomplicated influenza in England would be eligible for treatment with peramivir?

Have all relevant comparators for peramivir been included in the scope? How should best supportive care be defined?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom peramivir is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular

protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which peramivir will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider peramivir to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of peramivir can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction)

[ii] Public Health England (2015) 'Surveillance of influenza and other respiratory viruses in the United Kingdom: winter 2014 to 2015'. Accessed August 2015.
[iii] Royal College of General Practitioners (2015) 'RCGP Research and Surveillance Centre'. Accessed August 2015. Accessed August 2015.
[iv] Public Health England (2014) 'Public Health England and the NHS prepare for unpredictable flu season'. Accessed August 2015.