For information
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Legislative Council Panel on Health Services

Treatment for Wet Age-related Macular Degeneration Patients

PURPOSE

This paper briefs Members on the treatment for wet age-related macular degeneration (AMD) patients.

BACKGROUND

2. AMD is one of the leading causes of vision loss. It is an eye disease caused by degeneration of the retina due to old age. The disease can be classified into dry and wet forms. The dry form of AMD causes degeneration and atrophy of the macula of the eye leading to the loss of vision. At present, the medical profession has yet to establish any definite strategy to treat dry AMD. In the wet form of AMD, the loss of vision is caused by the abnormal growth of blood vessels in the macula. The ophthalmic profession estimates that there are about 3,000 new cases of wet AMD in Hong Kong each year. While the treatment options for wet AMD are still evolving, ophthalmologists have been using a group of drugs functioning as vascular endothelial growth factor (VEGF) inhibitors in the past few years to alleviate the conditions of the patients.

DRUG TREATMENT FOR WET AMD

3. There are two VEGF inhibitors commonly used by ophthalmologists to treat wet AMD, namely Ranibizumab (Lucentis) and Bevacizumab (Avastin). These drugs are administered by injection into the eyeball and they act against the growth of blood vessels in the macula to control the deterioration of vision. The two drugs are derived from the same monoclonal antibody and hence have similar molecular structure. They are both manufactured by the same company.

Ranibizumab (Lucentis)

4. Ranibizumab (Lucentis) is licensed in Hong Kong for the treatment of wet AMD in 2007. It is a self-financed drug on the Hospital Authority (HA) Drug Formulary (the Formulary) for wet AMD treatment. Ophthalmologists are

still developing the treatment regimen of the drug, including the optimal frequency of injection. At present, the number of injections can range from three to 12 per year, with each injection costing around $8,300.

Bevacizumab (Avastin)

5. Bevacizumab (Avastin) is licensed in Hong Kong for the treatment of colorectal cancer in 2005. It is a self-financed drug on the Formulary for cancer treatment. Although Bevacizumab (Avastin) is not licensed for the treatment of wet AMD, prescription of the drug beyond its licensed indication (or off-label use) for treating wet AMD is a common practice in various countries. For example, in the United States, around 60% of wet AMD patients received treatment with Bevacizumab (Avastin) in 2008.

6. As in most other jurisdictions, off-label use of drugs is not against the law in Hong Kong. As general principles, doctors should ensure that the drugs prescribed are clinically safe and appropriate for the patient, who should be properly consulted on the treatment. To better ensure clinical safety in the treatment of eye diseases, doctors can make reference to the international guidelines on the procedures of intravitreal administration of drugs. At present, HA does not prescribe off-label use of Bevacizumab (Avastin) for treatment of wet AMD. On the other hand, local universities have been using the drug on patients with wet AMD on a trial basis since 2005 and the off-label use is also common in the private medical sector. Each injection of Bevacizumab (Avastin) costs around $3,400. When administered intravitreally for wet AMD, each injection can be divided into multiple doses with each dose costing below $500. The frequency of injection of Bevacizumab (Avastin) is the same as that of Ranibizumab (Lucentis).

SAFETY AND EFFICACY OF DRUG TREATMENT FOR WET AMD

7. International clinical studies conducted by far show that the two VEGF inhibitors, Ranibizumab (Lucentis) and Bevacizumab (Avastin), are both safe and efficacious in treating wet AMD. Serious ocular adverse events are uncommon in the use of both drugs. There is also no significant statistical difference between them regarding the incidence of noted adverse events such as uveitis and endophthalmitis. While there is evidence that both drugs are efficacious in treating wet AMD, the treatment regimen of the drugs are still under deliberation by ophthalmic experts. The long-term safety, efficacy and cost-effectiveness of the drugs in treating wet AMD require the accumulation of more established clinical data to prove. To further ascertain the safety and efficacy of various VEGF inhibitors in treating wet AMD, large-scale

randomized controlled studies are being conducted in six overseas countries, including the United Kingdom, the United States and Germany.

INTRODUCTION OF DRUGS FOR TREATMENT OF WET AMD IN HA

8. HA seeks to ensure equitable access by patients to cost-effective drugs of proven safety and efficacy through implementation of the Formulary to standardize the drug policy and drug utilization in all HA hospitals and clinics. HA regularly appraises new drugs and reviews the list of drugs in the Formulary through its expert committees (including the Drug Advisory Committee and the Drug Utilization Review Committee) which comprise doctors, clinical pharmacologists and pharmacists. The review process adopts an evidence-based approach which takes account of the scientific evidence on safety, efficacy and cost-effectiveness as well as the actual clinical experience in the use of the drugs. The views of professionals and patient groups and other relevant considerations such as the principle of facilitating patients' choice are also taken into account.

9. In regard to the drugs for the treatment of wet AMD, Ranibizumab (Lucentis) and Bevacizumab (Avastin) are currently not listed as standard drugs for the disease in the Formulary. The optimum regimen of the drugs is still evolving while the long-term safety, efficacy and cost-effectiveness of the drugs require further study. HA will closely observe the developments in scientific evidence in the field, particularly the findings of the large-scale randomized controlled studies on various VEGF inhibitors being conducted overseas, in considering whether individual drugs should be included into the standard drug category of the Formulary based on the above-mentioned principles.

10. In the meantime, HA is planning to launch a special programme for wet AMD patients under suitable clinical conditions to receive subsidies to use relevant drugs for treatment on a trial basis through scientific research or other means. This programme will allow the accumulation of more local experience in the use of the drugs, thereby facilitating a more informed assessment of the safety, efficacy and cost-effectiveness of the drugs. This will also provide additional reference indicators to HA in considering whether to include the drugs concerned into the standard drug category of the Formulary. With additional funding from the Government, HA has reserved a sum of $12 million in 2010-11 for the special programme and is developing the details based on the views of ophthalmologists and the relevant clinical evidence and research findings.

11. We appreciate that patients have aspiration for including certain

drugs as standard treatment in the Formulary. As far as the treatment of wet AMD is concerned, HA will continue to keep abreast of the developments in the local and international scene and assess different treatment options based on clinical evidence. It will continue to maintain close collaboration with the ophthalmic profession so as to provide patients with appropriate support.

ADVICE SOUGHT

12. Members are invited to note the content of this paper.

Food and Health Bureau
Hospital Authority
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