RANZCO
The Royal Australian and New Zealand College of Ophthalmologists
THE MEDICAL EYE SPECIALISTS

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Pharmaceutical Benefits Division
Department of Health
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By email: PBSpostmarket@health.gov.au

**Public Consultation on Authority Required Medicines for the Post-market Review of Authority Required PBS Listings**

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to comment on the Review of Authority Required medicines.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and the Asia Pacific Region through continuing exceptional training, education, research and advocacy. Underpinning all of the College's work is a commitment to best patient outcomes, providing contemporary education, training and continuing professional development, evidence-based decision making, collaboration and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology services for patients.

**Purpose**

The treatments for eye conditions will be considered by the PBAC at the March 2015 meeting. RANZCO is pleased to provide input on which of the Authority Required listings should or should not be considered for movement to an Authority Required (Streamlined) listing or be unrestricted. This submission specifically focusses on issues relating to the authority approvals process for eye disease used for the treatment of age-related macular degeneration, bacterial keratitis and severe dry eye syndrome.

RANZCO is also advocating for broader reforms to the current authority system to reduce red tape and to improve efficiencies in specialist prescribing.

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## Macular degeneration

The PBS items included in Authority review for the treatment of macular degeneration are outlined in Table 1. Refer to Appendix 1 for PBS restriction summaries.

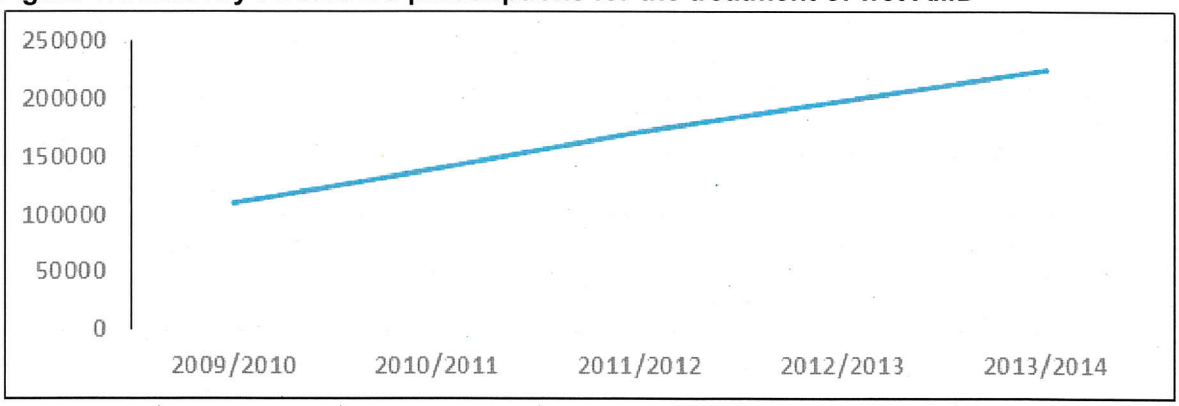
**Table 1: Authority PBS listings for the treatment of wet AMD**

| ATC Code | PBS Item | Drug name, strength and form |
|---|---|---|
| S01LA01 | 01349B | verteporfin 15 mg injection, 1 x 15 mg vial |
| S01LA04 | 01382R | ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial |
| S01LA05 | 02168D | aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial |

Age-related related macular degeneration (AMD) is a leading cause of blindness and vision loss in Australia [1]. One in seven Australians over the age of 50 years (1.15 million people) has some evidence of the disease and the incidence increases with age [1]. Neovascular (wet) AMD is due to choroidal neovascularisation which involves the growth of new blood vessels from the choroid capillary network into the neural retina, resulting in retinal detachment, subretinal and intraretinal oedema, and scarring. The PBAC recommended ranibizumab PBS listing for the treatment of subfoveal choroidal neovascularisation (CNV) due to age related macular degeneration on a cost-effectiveness basis against verteporfin (March 2007, PBAC PSD). Aflibercept was recommended on a cost-minimisation basis with ranibizumab (March 2012, PBAC PSD).

Trend analysis indicates that PBS/RPBS Authority prescriptions for Wet AMD are growing at a declining rate, refer to Figure 1. In 2013/14 financial year, the overall published expenditure to the PBS and RPBS for wet AMD treatments was equal to $350 million. Overall government expenditure has declined from $410 million in 2012/13 financial year, due to price changes.

**Figure 1: Authority PBS/RPBS prescriptions for the treatment of wet AMD**




| | | | | | |
|---|---|---|---|---|---|
| Growth | | 29% | 23% | 15% | 13% |

(Source: PBS statistics, data processing)

The Authority required PBS listings for wet AMD are currently managed by the Specialised Drugs Branch of the Department of Human Services. The first authority application for each eye must be made in writing or by telephone (supporting information to be provided by fax). The application must include: a completed authority prescription form; a completed Subfoveal Choroidal Neovascularisation (CNV) PBS Supporting Information Form; and a copy of the fluorescein angiogram. We note that the PBAC recently recommended that ranibizumab authority applications through the PBS for diabetic macular oedema and macular oedema secondary to retinal vein occlusion to be managed by the complex drug unit in a similar manner to Wet AMD (Source: July 2014 PBAC Outcomes).

The current process for authority scripts for is compromising the timely supply of medication for patients.

High burden of 'red tape' on prescribers

The current manual, paper based authority system for Wet AMD treatments is slow and cumbersome. A recent survey has indicated that most ophthalmologists are spending more than 1 hour a day on administration [2]. An AMA survey conducted in July 2013 found that of 1096 doctors, 14% reported spending 10-19 minutes a day seeking permission to prescribe authority with up to 25,000 consultations lost per month due to time spent on the phone awaiting prescription authorisations [3]. More time could be dedicated to patient care, without compromising the integrity or aims of the authority system. There is also the potential for application forms to be lost in the mail within current processes. In addition, any minor errors or omissions in completing the application form can also create delays prior script approval. An initial Authority approval may result in delays in patient treatment of over 10 working days, which is potentially compromising overall health outcomes

Excessive administrative burden for continuing patients

Patients receiving ongoing treatment for Wet AMD are continually monitored by ophthalmologists for changes in visual acuity and adverse events. A substantial reduction in the administrative burden on prescribers could be achieved by allowing streamlined authority processes in these cases.

**RANZCO Authority Listing Recommendations – Wet AMD**

RANZCO support the quality use of medicines for treatments of Wet AMD within PBS restrictions. The overall PBS expenditure represents a significant investment by the Australian Government in the prevention of avoidable blindness and improving patient vision. Current trend analysis indicates that the growth in prescriptions for Wet AMD is slowing and consistent with Australian epidemiological projections [1].

Initial Authority

- RANZCO supports the continued use of Authority items for the treatment of wet AMD prescribed by an ophthalmologist, given the overall financial cost to the PBS/RPBS.
- We support the adoption of internet based systems for Authorities approvals to improve overall administration efficiency and patient access. Entry of duplicate data will not be required for patients requiring treatment in both eyes. The ability to easily upload fluorescein angiogram tests should be considered.

Continued Authority

- RANZCO supports the use of Streamlined Authority items for continuing wet AMD scripts prescribed by an ophthalmologist. This will reduce the high burden of 'red tape' on prescribers and ensure patients receive timely supply of medications.

**Bacterial keratitis**

The PBS items included in Authority review for the treatment of bacterial keratitis are outlined in Table 2.

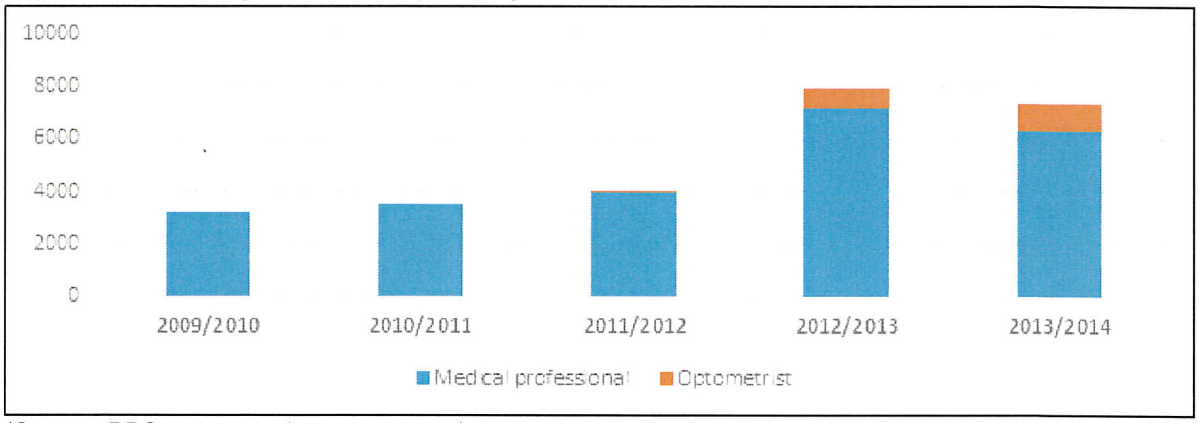
**Table 2: Authority PBS listings for the treatment of Bacterial keratitis**
Treatment criteria: Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

| ATC Code | PBS Item | Drug name, strength and form | Prescriber Type |
|---|---|---|---|
| S01AE01 | 05567B | ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL | Optometrist |
| S01AE01 | 08383F | ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL | Medical Professional |
| S01AE03 | 01217C | ciprofloxacin 0.3% eye drops, 5 mL | Medical Professional |
| S01AE03 | 05564W | ciprofloxacin 0.3% eye drops, 5 mL | Optometrist |

Ofloxacin and ciprofloxacin are broad based antibiotics, active against both Gram-positive and Gram-negative bacteria. In an effort to slow the development of bacterial resistance, restrictions on the use of fluoro-quinolones in humans and animals were introduced in Australia in the 1990s. Australia now benefits from a remarkably low rate of resistance to these agents for a range of pathogens. Ophthalmologists have played an important role in this success by agreeing to restrict the use of ofloxacin and ciprofloxacin eye drops to the treatment of bacterial infections of the cornea.

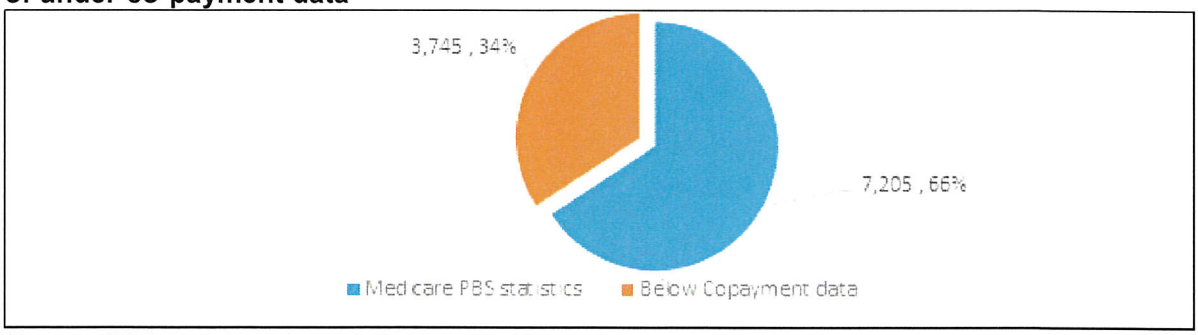
Trend analysis indicates that PBS/RPBS Authority prescriptions for bacterial keratitis have been growing, refer to Figure 2. The observed decline in PBS/RPBS prescriptions in 2013/14, may have resulted from price of ciprofloxacin falling below the general co-payment amount. In 2012/13, approximately a third of prescriptions were below the general co- payment amount and this proportion is likely to have increased in 2013/14. The overall published expenditure is modest, $70,000 in 2013/14.

**Figure 2: Authority PBS/RPBS prescriptions for the treatment of bacterial keratitis**




(Source: PBS statistics, data processing)

**Figure 3: Authority PBS/RPBS prescriptions for the treatment of bacterial keratitis inclusive of under-co-payment data**




(Source: PBS statistics, data processing and Under Co-payment data supplied by Pharmacy Guild)

Usage within PBS/RPBS restriction

Current optometry treatment guidelines for use of scheduled medicines recommend that optometrists should consider a specialist opinion for patients who may require long-term antimicrobial use [4]. This recommendation is inconsistent with the PBS restriction. PBS/RPBS data analysis indicates that the overall growth rate for fluoro-quinolones in 2013/14 prescribed by optometrists (34%) was significantly higher than the 5-year average growth prescribed by medical professionals (22%). The overall prescription base prescribed by optometrists is low, but inappropriate prescribing by optometrists may be occurring.

**Consistent with the current PBS/RPBS restriction, RANZCO considers that the supervision of the use of fluoro-quinolones by an ophthalmologist is essential.**

Treatment management

Patients who suffer from microbial keratitis are typically either patients who have suffered ocular trauma, contact lens wearers or patients with ocular surface disease [5]. It is uncommon for infection to occur in otherwise a normal eye. Management of microbial keratitis also involves the concomitant management of trauma and ocular surface disease and is therefore beyond the scope of optometrists.

Gram-negative infections account for only 20% of cases of infection in contact lens wearers and 6% of trauma. Further, 1 in 10 cases of microbial keratitis are polymicrobial, such that fluoro-quinolone monotherapy in these patients is inadequate [6]. MRSA is being increasingly recognised as a cause of microbial keratitis. Fluoro-quinolones have poorer coverage of gram-positive organisms such that management requires fortified vancomycin for MRSA or fortified cephalothin for other gram-positive organisms. Inappropriate management of microbial keratitis can result in cavernous sinus thrombosis due to retrograde spread of organisms from the eye to the brain, this has a significant mortality rate. Side-effects of fluoro-quinolone also include corneal melting and deposits, which can lead to irreversible loss of vision.

Fluoro-quinolones have been reported enhance the effects of oral anticoagulants, warfarin or its derivatives [7]. The patient risk may vary with the underlying infection, age and general status of the patient so that the contribution of ciprofloxacin to the increase in INR (international normalised ratio). When these products are administered concomitantly, prothrombin time or other suitable coagulation tests should be closely monitored by a medical professional.

Bacterial resistance

As well as the benefits to individual patients, the current PBS restriction has proved successful in minimising inappropriate prescribing and thus lowering the risk of the development of resistance to these valuable drugs [8]. Review by an ophthalmologist allows a corneal scrape to be performed which has the benefits of providing important epidemiological data on the microbes responsible for microbial keratitis and their sensitivity/resistance patterns. This assists the selection of the most appropriate targeted therapy and the rationalisation of intensive drug regimens resulting overall economic savings to the Australian community.

We believe that the broadening of unsupervised prescribing rights or Streamlining Authority item codes for optometrists will encourage both the empiric use of quinolones before appropriate specimens are taken and their increased use for less threatening conditions such as blepharitis, conjunctivitis and dacryocystitis.

Patient access

In our experience, microbial keratitis (corneal infection) are currently managed well and patients both rural and city based are typically able to be seen urgently by ophthalmologists.

**RANZCO Authority Listing Recommendations - bacterial keratitis**

- Australia now benefits from a remarkably low rate of antibiotic resistance. Ophthalmologists have played an important role by restricting the use of ofloxacin and ciprofloxacin eye drops to the treatment of bacterial infections of the cornea. RANZCO supports the use of Streamlined Authority items for ofloxacin and ciprofloxacin prescribed by Ophthalmologists. This will reduce overall the administrative burden for busy specialists and improve access to patients experiencing ocular trauma.
- RANZCO supports the continued use of Authority items for the treatment of bacterial keratitis prescribed by optometrists which require ophthalmologist supervision. This will ensure effective quality use of medicines and the inclusion of appropriate safeguards to minimize antibiotic resistance rates in the future.
- RANZCO supports ongoing monitoring of prescription for items used to treat bacterial keratitis.



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**Severe dry eye syndrome**

The PBS items included in Authority review for the treatment of severe dry eye syndrome are outlined in Table 3. All review items include extended maximum quantities and repeats.

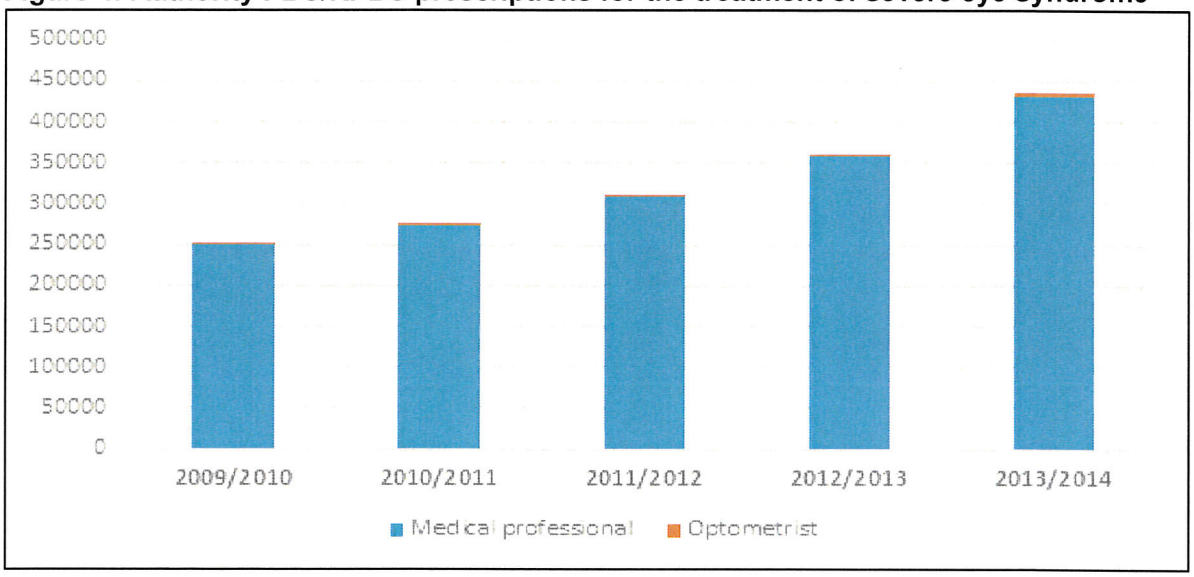
**Table 3: Authority PBS listings for the treatment of severe dry eye syndrome**

| ATC Code | PBS Item | Drug name, strength and form |
|---|---|---|
| **S01XA20** | **02090B** | carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses |
| **S01XA20** | **02171G** | sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL |
| **S01XA20** | **02184Y** | sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL |
| **S01XA20** | **05502N** | carbomer-974 0.3% eye gel, 30 x 500 mg unit doses |
| **S01XA20** | **05504Q** | carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses |
| **S01XA20** | **05505R** | carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses |
| **S01XA20** | **05506T** | carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses |
| **S01XA20** | **05509Y** | carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses |
| **ATC Code** | **PBS Item** | **Drug name, strength and form** |
| S01XA20 | 05510B | carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses |
| S01XA20 | 05521N | dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses |
| S01XA20 | 05532E | polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses |
| S01XA20 | 05545W | soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations |
| S01XA20 | 05560P | polyethylene glycol-400 0.25% (1 mg/0.4 mL) eye drops, 20 x 0.4 mL unit doses |
| S01XA20 | 05561Q | carmellose sodium 0.5% (2 mg/0.4 mL) + glycerol 0.9% (3.6 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses |

In Australia, about one adult in 10 is affected with dry eye syndrome [9]. This occurs when the eye does not produce enough tears or the tear quality is poor. Possible causes include: medications certain medical conditions such as Bell's Palsy, autoimmune diseases such as lupus, age, smoking, climate, vision correction surgery or long-term contact lens wear [9]. Severe cases of dry eye syndrome may cause complications including exposure keratopathy and ulceration of the cornea. Ophthalmologists have extensive medical training, whereby patient history and comorbidities are extensively considered in treatment selection and ongoing management.

Trend analysis indicates that PBS/RPBS Authority prescriptions for severe dry eye syndrome are growing at an increasing rate, refer to Figure 4. In 2013/14 financial year, the overall published expenditure to the PBS and RPBS for treatments was equal to $13 Million. Overall government expenditure has increased from $11 million in 2012/13 financial year.

**Figure 4: Authority PBS/RPBS prescriptions for the treatment of severe eye syndrome**




(Source: PBS statistics, data processing)

Medical professionals currently may prescribe streamlined Authority codes for severe dry eye syndrome with increased number of repeats and optometrists require Authority approval. The PBS items included in Authority review for the treatment of severe dry eye syndrome include items below the general co-payment amount ($36.90) yet the proportion is small (3%). Based on PBS data analysis, the overall growth rate for severe dry eye treatments in 2013/14 prescribed by optometrists (59%) was significantly higher than the 5-year average growth prescribed by medical professionals (15%), noting a small base.

A 2009 review of the streamlined authority system indicated that the introduction of the system had not changed medical professionals prescribing patterns and GP prescribing rates [10]. RANZCO supports RACGP position that there is strong evidence that the newly streamlined system giving GPs easier access to PBS authority items and does not result in inappropriate or over-prescribing [11]. The Productivity Commission Review in 2009 identified the PBS authority system as an unnecessary administrative burden for General practitioners and has recommended it be removed [12].

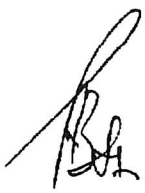
**Summary of Recommendations – severe dry eye syndrome**

- RANZCO supports the continued use of streamlined Authority items for the treatment of Severe dry eye syndrome by medical professionals. Ophthalmologists should also be consulted when patients require extended treatment for severe dry eye syndrome. We also consider that the high overall economic cost to the government and increasing growth in prescriptions may not support a move to restricted benefit for items with increased maximum quantities.
- RANZCO supports the continued use of Authority item codes for optometrists given the high growth in prescriptions and the clinical requirement for collaboration with an ophthalmologist.

**Conclusion**

RANZCO is pleased to provide input on which of the Authority Required listings should or should not be considered for movement to an Authority Required (Streamlined) listing or be unrestricted for eye disease. We are also advocating for broader reforms to the current authority system to reduce red tape and to improve efficiencies in specialist prescribing.

Yours sincerely,



Dr Stephen Best
**President, RANZCO**

**Appendix 1: PBS restriction Macular Degeneration**

Authority Required: Subfoveal choroidal neovascularisation (CNV)

| | |
|---|---|
| Clinical Criteria | • The condition must be due to age-related macular degeneration (AMD).<br>• The condition must be diagnosed by fluorescein angiography. |
| Treatment criteria | • Must be treated by an ophthalmologist.<br>• The treatment must be the sole PBS-subsidised therapy for this condition.<br>• Authority approval for initial treatment of each eye must be sought. |
| First Authority Application | • The first authority application for each eye must be made in writing or by telephone. |

**References**

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