

PRACTICE GUIDANCE: AZITHROMYCIN



Royal
Pharmaceutical
Society
of Great Britain

Following reclassification from prescription-only to pharmacy medicine status, azithromycin 500mg is now available for sale over the counter (OTC) from pharmacies. This guidance covers different routes of azithromycin supply through pharmacy. It takes into account the requirements of the Code of Ethics and outlines important points to consider when counter prescribing. Supply is also considered in the context of any national policy differences relating to chlamydia services.

This guidance forms a sub-section of the RPSGB practice guidance on sexual health expected to be published in 2009.

1. BACKGROUND

Genital *Chlamydia trachomatis* infection is the most commonly diagnosed bacterial sexually transmitted infection (STI) in genitourinary medicine (GUM) clinics in the United Kingdom. The number of diagnoses of uncomplicated genital chlamydial infection in GUM clinics has risen steadily since the mid-1990s.

All sexually active individuals are at risk of chlamydia. Risk factors for infection includes age under 25 years, new sexual partner or more than one sexual partner in the past year, a new sexual partner being more important than number of partners, and lack of consistent use of condoms.¹

As most people are asymptomatic, large proportions of cases remain undiagnosed. Untreated genital chlamydial infection may have serious long-term consequences, especially in women in whom it is a well-established cause of pelvic inflammatory disease (PID), ectopic pregnancy and infertility. The annual cost of chlamydia and its consequences in the United

Kingdom is estimated to be more than £100 million.²

'Choosing health through pharmacy'³ identified the need for redesign of sexual health services in **England** and highlighted public demand for greater access to sexual health advice through pharmacies.

The report highlighted that:

'Chlamydia infection rates are increasing, particularly in those under 25 years of age. The development of appropriate sexual health services for this group in pharmacies could significantly increase their access to confidential professional advice and testing, leading to higher rates of detection of sexually transmitted infections and improved self-care'.

In **Scotland**, the Scottish Government's sexual health strategy document 'Respect and Responsibility: Strategy and Action Plan for Improving Sexual Health'⁴ also recognised the sharp rise in chlamydia incidence and advocated more local services. Local NHS

boards piloted successful testing and treating from community pharmacies and in August 2008 the public health service of the community pharmacy contract was extended to provide free access to emergency hormonal contraception and free testing for / treatment of chlamydia infection (age limits apply). See '2. Routes of azithromycin supply'.

Wales is currently developing a Strategic Framework for Public Health which will address a range of public health themes including sexual health services.

NHS commissioning of community pharmacy to provide chlamydia testing, and in some areas treatment, is targeted on the whole to those under 25 years of age and depends upon local arrangements. The reclassification of azithromycin sits alongside existing services and provides opportunity for extending access to testing and treatment for chlamydia via community pharmacy.

2. ROUTES OF AZITHROMYCIN SUPPLY

There are five routes by which individuals can currently obtain azithromycin:

- As a Pharmacy (P) medicine for individuals 16 years or over
- As a prescription-only medicine (POM) either privately or via an NHS service including genitourinary (GUM) clinics or general practice
- As a POM through Patient Group Directions, via NHS Walk-in Centres, community contraception clinics (family planning clinics) and some community pharmacies
- Via the National Chlamydia Screening Programme (NCSP) in England – this is a free NHS service to the under 25s (and their partners of any age). It aims to ensure that young people are aware of their risk of acquiring chlamydia, its potential reproductive complications and have access to screening, prevention and treatment services in a variety of healthcare and non-healthcare settings. Not all testing sites offer treatment. Treatment is through a Patient Group Direction and sites can include community pharmacy.



- Via the sexual health service within the community pharmacy contract in Scotland – a free testing / treatment service. The chlamydia testing service is targeted at any individuals aged 15 to 24 years. The service allows for the testing of the individual and any current sexual partner(s). The chlamydia treatment service is available via a national Patient Group Direction to any individual aged 13 years or over. The service allows for the treatment of the individual and any current sexual partner(s) as per local NHS Board arrangements.

Clamelle® chlamydia service pharmacy model (OTC supply)

The Clamelle® chlamydia service is a private UK-wide service that is paid for by the customer.

The service is run jointly by Actavis, the National Pharmacy Association (NPA), which manages registrations, and Gordon Laboratory Group (GLG), an accredited private laboratory which carries out the

testing, manages the test results and the customer database.

Actavis are only distributing OTC azithromycin to pharmacies registered on the Clamelle® chlamydia service. It is the first reclassification, where an accredited laboratory test is required to confirm diagnosis before treatment is supplied.

Further information on registration to the service is available from the NPA Information helpline: 01727 891800.

3. LINKING WITH LOCAL NETWORKS

It is important that all health care professionals involved in sexual and reproductive health services provide consistent information. Pharmacists are therefore encouraged to take the lead in linking community pharmacies into existing local networks. Pharmacists should be fully aware of all local services in order to signpost patients appropriately. It is important to consider working with other agencies to explain the new pharmacy service, access any locally produced information, ensure that referral criteria and advice are consistent with other local service providers, and confirm that their contact details are included in any leaflets containing lists of local services and contact points.

4. CODE OF ETHICS

Pharmacists are reminded of the principles of the 'Code of Ethics for Pharmacists and Pharmacy Technicians' and 'Professional Standards and Guidance Documents' that support and supplement aspects of the Code (<http://www.rpsgb.org.uk/protectingthepublic/ethics/>).

In terms of azithromycin supply, particular attention is drawn to the sections covering: patient confidentiality, showing respect for others, and acting within the boundaries of professional knowledge and competence.

Robust procedures must be in place to protect the confidentiality of information that is received, stored, sent or destroyed. Customers also have the right to expect that any records about them are held securely and are kept out of sight of patients, members of the public and any other person who should not have access to them. Security measures must be appropriate to the location where the confidential information is being stored.

The Clamelle® chlamydia service consists of two components:

CLAMELLE® CHLAMYDIA TEST KIT

Test kits are bought from the pharmacy (these can be available for self-selection) and posted off by the customer to the laboratory. Customers may choose to receive a result letter by post or go to a pharmacy participating in this service to obtain their result.

Diagnosis of chlamydia is confirmed by a laboratory Nucleic Acid Amplification Technique (NAAT) test - a urine test which detects the nucleic acid of the *Chlamydia trachomatis* bacterium.

CLAMELLE® AZITHROMYCIN 500MG TABLETS

The OTC product is indicated for men and women (aged 16 years and over) who are asymptomatic and who have tested positive for genital *Chlamydia trachomatis* (eg using Clamelle® test). It is also indicated for epidemiological treatment of their sexual partners (without needing to take a test).

Customers need to present with either their test result letter or their verification tear-off slip from their test request form and the pharmacist should verify their positive test result on the database. In the case of partners, a partner notification slip, containing the index patient's Unique reference Number (URN) is required.

Individuals who are NHS chlamydia test-positives and their partners (on production of a recognised NHS partner notification slip) may purchase azithromycin provided they complete a Clamelle® NHS proforma and satisfy criteria for supply as set out in the Clamelle® chlamydia service training material.

RECORD-KEEPING, HEALTH PROTECTION AGENCY (HPA) AND ANONYMISED DATA PROVISION

Pharmacists participating in the Clamelle® chlamydia service should record any sales of azithromycin on the GLG Clamelle® database, through the secure web portal. If supply has been made to NHS test-positives or their partners, the pharmacist is responsible for sending the completed NHS proforma back to the originating NHS testing site.

The HPA counts how many people in the UK have chlamydia, as part of routine communicable disease surveillance and protecting public health. Anonymised details of test results and treatment supplies, but not name or contact details, are provided by the private laboratory to the HPA. This is the same as with NHS chlamydia testing. Patient consent is not required for this. This is covered under the Control of Patient Information Regulations 2002. The test kit patient information leaflet explains this to customers.

5. COMMUNICATION - PRIVACY AND CONFIDENTIALITY

Pharmacy users of all ages are entitled to a confidential consultation with their pharmacist, although not all pharmacy users will be aware of this.

Pharmacists may therefore consider advertising that all advisory services and consultations are confidential and that, where appropriate, a private area is available.

Pharmacists are encouraged to display a notice in the pharmacy encouraging pharmacy users to inform a member of staff if they require a more private consultation for any purpose. The dispensary should not be used for this purpose because of security risks in relation to medicines and patient information.

6. PRACTICE POINTS

OTC AZITHROMYCIN

- Training on the pharmacy service model should involve all pharmacy staff as they may receive enquiries about the service and be involved in the sale of test kits.
- Verifying an individual's chlamydia test result, the one to one sexual health consultation and requests for supply of OTC azithromycin should be referred to the pharmacist.
- OTC azithromycin is indicated for men and women (aged 16 years and over) who are asymptomatic and who have tested positive for genital *Chlamydia trachomatis* infection (eg using Clamelle® test). Also indicated for epidemiological treatment of their sexual partners (aged 16 years and over) without

needing to take a test.

- OTC azithromycin is taken orally as a single 1g dose as soon as possible after confirmed diagnosis.
- If the NAAT test was carried out correctly (at least two weeks after unprotected intercourse) individuals may request another test because they have had another incident of unprotected intercourse or because they wish to check that the original infection has cleared following treatment. In the first scenario, advise the individual of the two week window between unprotected intercourse and testing (see 'Practice Points General – All Routes of Azithromycin Supply'). In the second scenario, advise the individual that another test is not necessary – as clinical guidelines per se.
- If an individual still chooses to have another test, it should not be repeated within 6 weeks of treatment. In this timeframe the NAAT test may still remain positive – although this may not necessarily mean active infection, it may be detecting the presence of nucleic acid of non-viable organisms that have been successfully treated.

GENERAL – ALL ROUTES OF AZITHROMYCIN SUPPLY

- Refer to Summary of Product Characteristics (different for P and POM products) for information on contraindications, interactions, side-effects etc. Pharmacists are reminded to send a yellow card report to the Medicines and Healthcare products Regulatory Agency if a serious adverse drug reaction is suspected.
- Consider counselling individuals (including

those with a negative test result) and providing pharmacy leaflets and advice on the following areas or signpost to local services as appropriate: information on regular / emergency contraception, sexual and reproductive health, follow-up care, testing and screening for other STIs.

- Chlamydia-positive individuals and their partner(s) should abstain from all sex (vaginal, oral, anal sex and using sex toys) until both (all) of them have been treated and have waited for 7 days after the last person of the partnership has been treated.
- It may take up to two weeks for chlamydia infection to be detected by the NAAT test after unprotected exposure.⁶ It is advisable for individuals to take this into consideration when deciding to actually use the test kit. If the episode of unprotected sex was recent they may need to wait to use their test kit until two weeks after this exposure, otherwise they may get a false negative result.
- Clinical guidelines do not recommend follow-up testing for chlamydia after treatment with azithromycin (or other treatment) unless re-infection is suspected. The customer may still choose to undertake a follow-up chlamydia test to confirm they are clear of infection but this is a personal choice and is not a clinical requirement. See 'Practice Points – OTC Azithromycin'.
- Familiarise yourself with the RPSGB Guidance on Child Protection. (<http://www.rpsgb.org/pdfs/childprotect-guid.pdf>)
- Familiarise yourself with the RPSGB 'Practice Guidance on the supply of emergency hormonal contraception as a

Pharmacy medicine' (<http://www.rpsgb.org/pdfs/ehcguid.pdf>) and updated advice on advance provision (<http://www.rpsgb.org/pdfs/pr061218.pdf>)

- Familiarise yourself with the different 'Routes of azithromycin supply' / any national policy differences relating to chlamydia services. See '8. Training resources' at end of guidance.

7. CASE STUDIES

Case study 1

A 15-year-old girl presents to the pharmacy with a chlamydia service partner notification slip, informing her that a sexual partner of hers had tested positive for chlamydia. She wants some advice about what to do next.

Considerations

- This girl is not eligible for OTC azithromycin as she is less than 16 years of age (refer to licensed indications in Summary of Product Characteristics).
- Explain that the pharmacist can discuss issues relating to sexual health, signpost to a local sexual health and reproductive service provider etc.
- Familiarise yourself with the RPSGB Guidance on Child Protection.
- England. Anyone under 25 years of age can receive free screening / treatment under the National Chlamydia Screening Programme (England-only) from participating venues. Alternatively, advise a visit to a local sexual health and reproductive health service (e.g. local GP, GUM clinic, sexual health venue) to test for other STIs / receive free treatment and advice.



- Scotland. A free chlamydia testing and treatment service is available via a national Patient Group Direction for individuals aged 15-24 years and their partners aged 13 years or over as per local NHS Board arrangements.

- Wales. Everybody (all ages) can get free prescriptions.

Case study 2

A 35-year old woman presents to the pharmacy and requests a chlamydia test kit. She had unprotected sex last night with a new partner and is also concerned about pregnancy.

Considerations

- This woman may be suitable for testing / treatment via the Clamelle® chlamydia service.
- Explain how it may take up to two weeks for chlamydia to show up after the infection, so she should wait to use the test kit till at least two weeks have passed since the episode of unprotected sex.
- Offer a consultation with a pharmacist to discuss emergency hormonal contraception supply, advice on safe sex, signposting etc.
- Provide information on local sexual and reproductive health services (e.g. GP, GUM clinic, sexual health venue) for treatment, advice and further STI testing.

Case study 3

A 26-year old man presents to the pharmacy

with a Clamelle® positive test result letter. He asks for advice.

Considerations

- The pharmacist should be directly involved in verifying the test result and carrying out the sexual health consultation.

- Verifying the test result is carried out online via the GLG Clamelle® database using the individual's URN (this can be found on the results letter), first part of the postcode and year of birth.

- A one to one sexual health consultation needs to be carried out for all chlamydia positive individuals.

- The customer should be advised to treat the infection as soon as possible, either through the pharmacy with OTC azithromycin or supply via a local sexual health and reproductive service provider. If the man is eligible for OTC azithromycin and it is supplied, the sale should be recorded on the GLG Clamelle® database.

- The customer should be given Clamelle® Partner Notification (PN) slip(s) to give to his partner(s) so his partner(s) can get treatment (e.g. with OTC azithromycin without the need for testing, or through local sexual health and reproductive service providers). The URN should be written on the PN slip(s) and the number of PN slips given to the index patient should tally with the number of sexual partners they have had in the last six months. Stamp the customer's test result letter so that it cannot be re-used

to request a further supply of OTC azithromycin.

- Provide information on local sexual and reproductive health services (e.g. GP, GUM clinic, sexual health venue) for treatment, advice and further STI testing.

8. TRAINING RESOURCES

1. Clamelle® Chlamydia service – Chlamydia Pharmacy Training Pack (Actavis UK Ltd)
2. NPA Chlamydia Resource Pack. Contact NPA Information helpline: 01727 891800.
3. National Chlamydia Screening Programme (NCSP): www.chlamydia-screening.nhs.uk
4. UK National Guideline for the Management of Genital Tract Infection with Chlamydia trachomatis: www.bashh.org
5. The Manual for Sexual Health Advisors: www.ssha.info/public/manual/index.asp
6. NHS Community Pharmacy Contractual Framework Enhanced Service (England & Wales) – Chlamydia screening and treatment: http://www.psn.org.uk/data/files/PharmacyContract/enhanced_service_spec/en14_chlamydia_screening_service_final_14_july_08.pdf
7. Community Pharmacy Scotland. Pharmaceutical Services Specification. Public Health Service. Sexual Health Service (emergency hormonal contraception and chlamydia testing / treatment service) http://www.communitypharmacyscotland.org.uk/_resources/files/legislation/Annex%20C%20Service%20Specification%20for%20Sexual%20Health%20Service.pdf
8. CPPE: <http://www.cppe.ac.uk/>

9. NES Pharmacy

<http://www.nes.scot.nhs.uk/pharmacy/>

10. WCPPE:

<http://www.cf.ac.uk/phrmy/subsites/WCPPE/>

11. fpa: <http://www.fpa.org.uk/>

9. ADDITIONAL SOURCES OF INFORMATION

(including sources for leaflets)

1. fpa: <http://www.fpa.org.uk/>
2. Brook: <http://www.brook.org.uk/>
3. NHS Direct: <http://www.nhsdirect.nhs.uk/>
4. NHS 24: <http://www.nhs24.com/content/>
5. Terrence Higgins Trust (THT): <http://www.tht.org.uk>

10. REFERENCES

- ¹UK National Guideline for the Management of Genital Tract Infection with Chlamydia trachomatis. British Association for Sexual Health and HIV, 2006. <http://www.bashh.org/documents/61/61.pdf>
- ²National Chlamydia Screening Programme. <http://www.chlamydia-screening.nhs.uk/>
- ³Choosing health through pharmacy – A programme for pharmaceutical public health 2005 – 2015. Department of Health, 2005. (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4107494)
- ⁴Respect and Responsibility: Strategy and Action Plan for Improving Sexual Health. Scottish Executive, 2005. (<http://www.scotland.gov.uk/Publications/2005/01/20603/51182>)
- ⁵Further information on the National Chlamydia Screening Programme (including training materials and types of participating venues) is available via: <http://www.chlamydia-screening.nhs.uk>
- ⁶Testing for Chlamydia – the “window period”. British Association for Sexual Health and HIV, 2008. <http://www.bashh.org/documents/1743/1743.pdf>