



# Best Practice Guidelines

For Online Prescribing  
of 5-alpha-reductase  
Inhibitors for  
Androgenic Alopecia

**DiCE**

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## Introduction

These guidelines have been created by the UK Digital Clinical Excellence Forum 'DiCE', which incorporates the leading independent providers of digital services in the UK.

They have been designed to support the online industry in maintaining the highest standards of quality and safety in this rapidly expanding sector of healthcare provision and were developed in close alignment with professional bodies and regulators. They will be complementary to existing professional and regulatory standards and support providers in practically demonstrating how regulatory standards are being met through specific examples of online provision.

This industry-led approach by the legitimate and regulated online sector will help distinguish between online providers that the public can trust from those who could potentially do harm and provide service users with quality and safety assurance.

## About Digital Clinical Excellence

The UK Digital Clinical Excellence Forum 'DiCE' was established in March 2019 to provide a collective voice and support network for the growing community of UK digital healthcare providers. This network aims to drive excellence in digital care standards to support clinical care improvement and safety in digital healthcare, and now connects the clinical leadership of independent sector online providers.

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## **About this document**

This Best Practice Guidance is based on collective expert opinion from participants in the Digital Clinical Excellence (DiCE) Working Group convened in a virtual meeting on October 5th, 2023, and at follow-up meetings on November 1st and November 28th, 2023. The purpose of the meetings was to gather and review existing evidence and practices, and to form a consensus on a best practice approach to enhance the quality and safety of online provision with the independent online pharmacy sector.

This guidance has been developed specifically for digital asynchronous prescribing of 5-alpha-reductase (5AR) inhibitors for the treatment of male pattern hair loss (androgenic alopecia). Other types of prescribing of 5AR inhibitors falls outside the scope of this document.

## **About digital asynchronous prescribing**

In the UK, digital asynchronous prescribing is subject to the same legal requirements and regulations as in-office primary care prescribing. The Care Quality Commission regularly carries out inspections of registered digital and online providers to assess the quality of care being offered. This includes assessments of how safe, effective, caring, responsive and well-led the service being provided is [1].

When conducted in a well-regulated setting with good risk management systems, routine reviews to drive continuous learning improvement, and careful consideration of how information is provided to patients, asynchronous prescribing is effective in replacing in-office primary care visits and providing timely care and increased convenience for patients [2]. Some studies have shown greater compliance with prescribing guidelines with online, form-based assessments than in-office visits, driving improvements in, for example, antimicrobial stewardship [3–7].

For more general information on digital asynchronous prescribing, refer to guidance and standards developed by UK regulatory and professional bodies:

- Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (General Pharmaceutical Council, 2022) [8].
- Policy for providing medicines online (Royal Pharmaceutical Society, 2019) [9].
- Remote prescribing high-level principles (General Medical Council, 2019) [10].
- Standards for identity checking for asynchronous online primary care providers (Digital Healthcare Council, 2019) [11].

## 1. What is androgenic alopecia?

Androgenic alopecia, also known as male pattern hair loss, is the most common type of alopecia worldwide [12]. It is estimated to affect up to 60% of men by the age of 50 years [13]. Androgenic alopecia can have a profound psychological and social impact, particularly in younger men and men with rapidly progressing hair loss [14]. An increasing number of men are seeking treatment for androgenic alopecia, including hair transplantation and drug therapies to slow down or reverse hair loss. Studies show that younger men are more likely to turn to an online prescriber than to access treatment through traditional care [15,16].

Drug therapies for male pattern hair loss include:

- Topical or oral minoxidil, which works by increasing blood flow to hair follicles [17,18] and
- Oral 5-alpha-reductase (5AR) inhibitors, which work by blocking the 5AR enzyme from metabolising testosterone to dihydrotestosterone (DHT), a more potent androgen known to contribute to progressive hair loss [19].

Whilst topical minoxidil is an over-the-counter product, oral minoxidil and 5AR inhibitors are not available on the NHS for use in male pattern hair loss and require a private prescription. Registered online prescribers in the UK currently offer two oral 5AR inhibitors: finasteride and dutasteride. Finasteride is more commonly prescribed for men with hair loss, since the use of dutasteride is 'off-label' for these patients [20,21].

Dutasteride is a more potent inhibitor of 5AR and is, in theory, a more effective treatment for hair loss than finasteride.20,21 The two drugs appear to have comparable side effect profiles [22].

## 2. Why is a best practice approach needed?

In May 2017, the MHRA issued a [Drug Safety Update](#) based on reports of depression and, in rare cases, suicidal thoughts in men taking finasteride for androgenic alopecia with and without a history of depression [23]. An increased risk for self-harm and depression has also been reported in men taking 5AR inhibitors for prostate enlargement [24].

The use of 5AR inhibitors has also been linked with an increased risk of male breast cancer and sexual dysfunction, including decreased libido, erectile dysfunction, and ejaculation disorders [20–22].

The MHRA recommends that prescribers should advise patients to stop taking finasteride immediately if they develop depression and to inform a healthcare professional [23].

While it is hoped that all online providers have protocols in place for regular monitoring of men prescribed 5AR inhibitors for hair loss, it is the opinion of the DiCE membership that developing best practice guidance to establish a base-level of care across the industry would be beneficial. This includes recommendations for screening patients for mental health issues and other relevant medical conditions, as well as recommendations for monitoring and review of prescriptions.

### **3. Considering the patient journey**

Men seeking a prescription for finasteride or dutasteride from an online provider are likely to have researched hair loss treatment options on the internet, where poor-quality research from unqualified sources is prolific.

It is important for online prescribers to distinguish themselves from the noise and provide trustworthy and scientifically rigorous information. A recent study from Germany of 2,904 men seeking finasteride treatment from an online provider found that 30.5% cited trust in the pharmacy as a motivating factor; by comparison, medication cost was cited by 27.7%. [16].

The same study found that most men accessed the digital health platforms directly by typing in the URL rather than through search engines, referrals, social media or paid ads [16].

### **4. Recommendations from the DiCE Working Group**

#### **4.1 Who should follow these recommendations?**

The following recommendations are intended as a best practice guide to developing form-based assessments to allow online providers to safely prescribe 5AR inhibitors for male pattern hair loss. They are not intended to be comprehensive of all possible considerations, or to impose a universal screening process across all providers. For example, some providers may include further considerations (e.g. hair loss classification systems such as the Norwood scale [25]) in the screening process.

These recommendations are intended to complement current prescribing information for finasteride and dutasteride. Online providers should always refer to the BNF and Summary of Product Characteristics before prescribing a 5AR inhibitor for male pattern hair loss.

#### **4.2 Recommendations for initial consultation and prescribing**

Although the clinical evidence is mostly for finasteride 1 mg (the licensed dose for hair loss [20]), it is the opinion of the Working Group that the same best practice approach applies in patients prescribed dutasteride 0.5 mg off-label.

Note that off-label prescription of any medication requires an adequate risk assessment, ensuring indemnity cover, and notifying the patient that the medication is being used off-label. Refer to the General Pharmaceutical Council guidance for more information [26].

## Recommendations

**A patient may be eligible for 5AR inhibitor treatment for male pattern hair loss:**

**– If they were assigned male at birth**

- 5AR inhibitors are not licensed for use in people assigned female at birth [20,21]

**– If they are aged 18 years or older**

- 5AR inhibitors are not licensed for use in children and adolescents [20,21]. The approval of finasteride 1 mg for androgenic alopecia was based on clinical studies in men aged 18–41 years with mild-to-moderate hair loss; however, an upper age limit for treatment has not been defined [20].
- If a prescriber implements an upper age limit for prescribing 5AR inhibitors in their practice, they should document their reasons.

**Use caution when prescribing a 5AR inhibitor for male pattern hair loss:****– If the patient reports a history of depression or suicidal thoughts during screening**

- Counsel the patient on the possible mental health side effects of 5AR inhibitors (see Section 2) [20,23,24].
- Signpost available NHS services and other sources of advice for depression.
- Follow the recommendations in Section 4.3 for monitoring and review of the customer's mental health and other side effects.

**– If the patient reports a history of liver disease during screening**

- Because 5AR inhibitors are extensively metabolised in the liver, increases in liver enzymes can occur during treatment [20,21].
- Advise the patient to consult their GP or private doctor for further investigation before prescribing.
- If further investigation indicates severe liver disease, 5AR inhibitors should not be prescribed. The effect of severe liver disease on the pharmacokinetics of 5AR inhibitors has not been studied [20,21].

**– If the patient is undergoing PSA monitoring**

- Advise the patient that use of a 5AR inhibitors can affect the results of tests to determine the levels of prostate-specific antigen (PSA) in the blood, and that they should inform their doctor before taking a PSA test [20,21].

**– If the patient has difficulty urinating (obstructive uropathy)**

- Advise the patient to consult their GP or private doctor for examination and further advice.

**– If the patient has a partner who is pregnant**

- Advise the patient that their partner should avoid touching broken finasteride tablets or leaking dutasteride capsules in case of contact with the active drug, as this may affect the baby's sex organs [20,21].

**– If the patient has a partner who is planning to become pregnant**

- Advise the patient that 5AR inhibitors can impact their fertility, but this is not common and usually resolves after stopping treatment [20,21,27].
- While on treatment, small amounts of active drug may be present in their semen, but it is not known whether exposure at time of conception can affect the development of a male foetus [20,21,27].

**Consider not prescribing a 5AR inhibitor for male pattern hair loss:**

- **If the patient has previously developed sexual dysfunction while taking a 5AR inhibitor**
  - Sexual dysfunction is a known side effect of 5AR inhibitors [20,21], and could potentially compound the risk of mental health issues while taking these medications.
- **If the patient has a history of prostate cancer or is undergoing investigation for prostate cancer**
  - Although the evidence is inconsistent, it has been suggested that 5AR inhibitors can increase the malignant potential of prostate cancer [20,21].
- **If the patient has a history of male breast enlargement (gynecomastia)**
  - Male breast enlargement is a known side effect of 5AR inhibitors [20,21].
  - The signs of gynecomastia are like those of male breast cancer, which has been reported in men taking 5AR inhibitors. [20,21].

**Do not prescribe a 5AR inhibitor for male pattern hair loss:**

- **If the patient is under 18 or assigned female at birth**
  - 5AR inhibitors are not licensed for use in these patients [20,21].
- **If the patient is already taking another 5AR inhibitor**
  - For example, for prostate cancer.
- **If the patient has a known hypersensitivity**
  - 5AR inhibitors should not be prescribed to patients with hypersensitivity to the active drug or to any of the other substances listed in the SmPC [20,21].



### 4.3. Recommendations for monitoring and review

Once the screening consultation is complete, eligible patients may be prescribed up to 6 months of once-daily finasteride 1 mg (168 tablets) or dutasteride 0.5 mg (180 capsules).

Based on the experience of DiCE Working Group members, most reports of side effects of 5AR inhibitors occur within the first 2 weeks of treatment and are self-reported by patients. However, it can take up to 6 months for patients to see any progress in terms of hair growth and prevention of further hair loss [20,21].

In terms of a best practice approach, there is a need to balance the risk of overlooking men who develop mental health issues while taking 5AR inhibitors and maximising the clinical value of contact points with patients.

The consensus among DiCE Working Group members is that screening should take place at the time of prescription refill, 3–6 months after starting treatment.

### Recommendations

#### **In addition to the product's patient information leaflet, online prescribers should provide men with:**

- Advice about stopping treatment if they develop depression or any other potentially serious side effect of 5AR inhibitors, and how they can seek help.
- Advice about the importance of checking for and reporting any changes in their breast tissue, such as lumps, pain or nipple discharge.
- Advice on how to self-report side effects of treatment to the MHRA using the Yellow Card online reporting tool for patients.

#### **Monitor patients at time of prescription refill (3–6 months after starting treatment)**

- Ask the patient whether they have perceived any improvement in their hair loss and reinforce that it can take up to 6 months to see an effect of treatment.
- Ask the patient if they have experienced any sexual side effects since starting treatment (e.g. low libido, erectile dysfunction or ejaculation disorders).
- Ask the patient if they have experienced any psychological side effects since starting treatment.
- Prescribers may wish to use a short, validated screening tool for depression (e.g., the 2-item Patient Health Questionnaire or a numerical rating scale).
- Consider repeating the initial screening process to ensure that continuing 5AR inhibitor therapy is right for them.

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