The Global Aware Group

Appropriate Care For Women With Androgen Excess

# Assessment and Diagnosis of Polycystic Ovary Syndrome (PCOS)

Polycystic ovary syndrome (PCOS) is a common, heterogeneous disorder affecting 6 to 21% of women worldwide[1*]

The global AWARE group is an independent panel of physicians with expert interest in the treatment of androgen excess in women. Formation of the AWARE group and its ongoing work is supported by Bayer AG.

## DEFINING PCOS

The Rotterdam criteria define PCOS by the presence of two of the following: irregular menses, hyperandrogenism (either clinical or biochemical) and polycystic ovary morphology, after exclusion of other androgen excess and related disorders and endocrine causes such as hyperprolactinemia

| Parameter | Phenotype | | | |
|---|---|---|---|---|
| | A | B | C | D |
| Hyperandrogenism (HA) | + | + | + | – |
| Ovulatory dysfunction (OD) | + | + | – | + |
| Polycystic ovary morphology (PCOM) | + | – | + | + |

Table adapted from Lizneva D et al, 2016

## 1. ASK

### Medical history

- Menstrual irregularity (intervals <21 days or >35 days; prolonged or heavy menstrual bleeding)[2]
- Ovulatory dysfunction (irregular intervals, intervals of <21 or >35 days; or delayed ovulation)[2]
- Previous treatment and/or self care (e.g. shaving, waxing)

Regular waxing or shaving can disguise the severity of hyperandrogenic skin symptoms such as hirsutism

## 2. ASSESS[3,5]

### Hyperandrogenic manifestations

- Clinical presence of skin symptoms such as acne, hirsutism, seborrhea and alopecia
- Biochemical evidence of elevated androgens

### Physical examination

- Body mass index (BMI)
- Waist/height ratio (WHR)
- Blood pressure (BP)

## 3. CONSIDER[6-10]

### Psychosocial impact

- Emotional wellbeing
- Quality of life

### Long term healthrisks

- Androgen excess, particularly if there is accompanying anovulation or PCOS may lead to increased risk of metabolic syndrome and endometrial hyperplasia or malignancy if left untreated[5]

Hyperandrogenic skin symptoms are associated with significant quality of life and psychological impairment

## 4. TEST[4,5] Investigations to confirm a diagnosis of PCOS remain the same regardless of phenotype

**Please note:** Use of these laboratory tests will be guided by local protocols and/or cost constraints according to clinical practice and availability.

| | |
|---|---|
| Ultrasound | To confirm PCOS<br>**NB** absence of ovarian morphology does not exclude diagnosis |
| Serum 17-hydroxyprogesterone (OHP)<br>24h urinary free cortisol<br>DHEA-S | To exclude other hyperandrogenic conditions<br>e.g. thyroid disease, non-classical congenital adrenal hyperplasia, adrenal or ovarian tumors, acromegaly, Cushing syndrome and late-onset androgenital syndrome (AGS) |
| Serum or urine human chorionic gonadotrophin (HCG) | To evaluate amenorrhea and exclude pregnancy |
| Anti-Mullerian hormone (AMH) 4h urinary free cortisol<br>Sex hormone binding globulin (SHBG)<br>Serum free IGF-1 | Other tests which may be helpful<br>e.g. AMH has an emerging role in predicting Ovarian Hyperstimulation Syndrome (OHSS) in IVF cycles or to consider the presence of granulose cell tumors |

### Metabolic assessment (following confirmation of PCOS)

- Complete lipid profile, including total cholesterol, low-density lipoprotein (LDL)-cholesterol, non-high-density lipoprotein (HDL)-cholesterol, HDL-cholesterol and triglycerides
- Oral glucose tolerance test (OGTT)
- Blood pressure

* When assessed using the Rotterdam criteria[2]

1. Lizneva D et al. Fertil Steril 2016;106(1):6–15; 2. Rotterdam ESHRE/ASRM-sponsored PCOS consensus workshop group. Hum Reprod. 2004;19:41–7; 3. Legro RS et al. J Clin Endocrinol Metabol. 2013;98(12):4565–92; 4. Goodman NF et al. Endocrine Pract 2015;21(11):1291–300; 5. Fauser BCJM et al. Am Soc Rep Med. 2012;97(1):28-38.e25; 6. Ekback MP et al. Dermatol. 2013;227:278-84; 7. Aktan S et al. Int J Dermatol. 2000;39:354–7; 8. Koo JYM and Smith LL. Pediatr Dermatol. 1991;8:185–8; 9. Stern RS. J Am Acad Dermatol. 2000;43:1042–8; 10. Kellett SC and Gawkrodger DJ. Br J Dermatol. 1999;140(2):273-82.

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# Essentials for safe and effective prescribing in the management of PCOS

## 5. EXPLAIN

### What to explain?

- The importance of lifestyle management including regular exercise and healthy eating behaviour
- The pathophysiology of symptoms in simple, patient-focused language
- How the treatments work
- The need for a follow-up plan

### Why?

- Lifestyle modification is important for all women affected by PCOS: moderate weight loss (5 to 10%) in women with PCOS can improve insulin resistance as well as androgenic and reproductive outcomes[4]
- Increasing patient knowledge helps to empower patients[11]
- Explaining how treatments work can help patients understand the importance of correct and consistent treatment, especially in long-term conditions[12]
- Skin symptoms such as acne and hirsutism often require long-term treatment[13]
- PCOS is associated with long-term metabolic and reproductive health risks[2]

## 6. MANAGE

### What to manage?

- Symptoms of clinical hyperandrogenism i.e. hirsutism, acne, seborrhea or alopecia
- Symptoms of biochemical hyperandrogenism such as endometrial or metabolic complications

- Use established treatment combinations for androgen excess and follow clinical guidelines and relevant criteria for use.
- Patients must be carefully screened before using any estrogen/progestogen combinations, and pregnancy must be excluded
- Further guidance on contraindications is available in the, **'WHO MEC for contraceptive use'**[16]

### Why?

- Effective treatment can help to improve the significant quality of life and psychological impairment associated with hyperandrogenic skin symptoms[14,15]
- To help reduce the risk of both reproductive and metabolic/cardiovascular consequences associated with long-term androgen excess disorders[3,11]

- EE in combination with progestogens with antiandrogenic potential (CPA, CMA, DNG or DRSP) are preferred treatment options[16,17]
- CPA combined with EE is indicated for the treatment of moderate to severe acne related to androgen-sensitivity (with or without seborrhea) and/or hirsutism, in women of reproductive age[16,18]

## 7. REFER IF

### What to refer?

- Abnormal findings (ovaries or endometrium) with clinical ultrasound
- Evidence of metabolic disorders

### Why?

- Further imaging procedures may be needed
- For effective assessment and treatment

EE: ethinylestradiol, CPA: cyproterone acetate, CMA: chlormadine acetate, DNG: dienogest

11. Chen J et al. Health Educ. Behav. 2016;43(1):25-3; 12. Brown MT and Bussell JK. Mayo Clin Proc. 2011;86(4):304-314; 13. Bitzer et al. [In preparation]; 14. Tartagni M et al. Fertil Steril. 2000;73(4):718-23; 15. Chung JP et al. J Pediatr Adolesc Gynecol. 2014;27(3):166-71; 16. World Health Organisation (WHO). Available at: http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/; 17. Yildiz BO. Semin Reprod Med. 2008;26:111–120; 18. Diane-35® Summary of Product Characteristics

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