Cannock Chase Clinical Commissioning Group
East Staffordshire Clinical Commissioning Group
North Staffordshire Clinical Commissioning Group
South East Staffordshire and Seisdon Peninsula Clinical Commissioning Group
Stafford and Surrounds Clinical Commissioning Group
Stoke-on-Trent Clinical Commissioning Group

INTERIM RECOMMENDATION FOR DRUG ADMINISTRATION DURING THE COVID-19 PERIOD

DRUG: Gonadotrophin Releasing Hormones (GnRH) agonists

The gonadotrophin releasing hormones such as Triptorelin**,** Goserelin acetate (Zoladex®), Leuprorelin acetate (Prostap®) are licensed for multiple indications. A comprehensive break down of licensed indications for each of these GnRH can be found at the end of the article (Appendix 1).

The RCGP has produced guidance[1] on workload prioritisation and assigns essential injections like GnRHs a '**GREEN**' rating (aim to continue) and local COVID LES arrangements for the North, South West and South East divisions concur with this.

Management of individual patients prescribed GnRHs will be dependent on the indication for which they are prescribed, the LES in place within your CCG and the practice's individual contractual position. The following information is for clinical guidance only and no change to the practice's current contractual arrangements or individual patient arrangements is suggested.

Formulary Status:
North Staffordshire Joint Formulary: AMBER- at the recommendation of specialist, triptorelin (Decapeptyl®)- first line choice. Goserelin (Zoladex®) & leuprorelin acetate (Prostap®) are AMBER- at recommendation of specialist.

South Staffordshire Formulary: AMBER- initiated by a Specialist but are suitable for continuation in Primary Care, leuprorelin acetate (Prostap®) & triptorelin (Decapeptyl®) - first line choices. Goserelin (Zoladex®) are AMBER- at recommendation of specialist.

Prostate Cancer:

BAUS guidance -COVID-19 strategy for the Interim management of Prostate Cancer[2]:

- Continue with current diagnostics and treatment protocols as long as possible.
- For hospitals where COVID-19 has not had significant impact, usual diagnosis and treatment should be maintained.
- Consider 6 monthly LHRH preparations.

UHNM Urology Advice:
UHNM Urology Consultant advises that use of monthly preparations is rare, locally patients are usually started on 3 monthly preparations, but 6 monthly preparations are considered. The BAUS guidance mentions migrating to a 6 month preparation. UHNM Urology Consultant advises there is no theoretical reason to expect a risk to any migration.

UHDB Urology Advice:
UHNM Urology Consultant advises minimising contacts as much as possible, therefore using the longest acting product available from the outset seems sensible.

Breast Cancer:

Aim to continue unchanged. Patient specific advice via the patient's oncologist.

Fertility Treatment:

For Staffordshire and Stoke-on-Trent CCGs, fertility drugs should not be prescribed in primary care. They are funded as part of the fertility treatment and administration will be managed by the fertility clinic.

Endometriosis and Uterine Fibroids:

GnRH agonists are only licensed for short-term treatment of endometriosis and uterine fibroids; contact the local gynaecology department for advice on patient specific management.

Gender Identity Disorders:

The Gender Identity Clinic (GIC)[3] has issued guidance on the management of patients during the COVID-19 pandemic. It suggest patients due to receive GnRH injections who display symptoms suggestive of Covid-19, or who are self-isolating, should inform their GP in advance of their appointment, NOT attend for their injection, and remain in self-isolation for the period currently recommended by government and the NHS.

Their injection should be given as soon as possible after they complete the recommended period of self-isolation.

A GnRH injection may be safely delayed for a several weeks, with a very low risk of a resumption of testosterone or estradiol release. Consult the patient individual clinic for patient specific management.

For further support and prescribing guidance, please contact the CCGs Medicines Optimisation team via email: nstccg.staffsmedicineoptimisationqueries@nhs.net

References:

1. CGP (2020). RCGP Guidance on workload prioritisation during COVID-19. https://www.dispensingdoctor.org/wp-content/uploads/2020/03/RCGP-workload-prioritisation.pdf

2. AUS (2020). COVID-19 strategy for the Interim management of Prostate Cancer Prepared by the BAUS Section of Oncology.https://www.baus.org.uk/_userfiles/pages/files/secure/BAUS%20Oncology%20COVID%2019%20Prostate.pdf

3. Gender Identity Clinic (2020) Issues around Hormone Therapy due to the coronavirus situation. https://gic.nhs.uk/gp-support/issues-around-hormone-therapy-due-to-the-coronavirus-situation/

4. Prescqipp (2014) B88. Luteinising hormone-releasing hormone (LHRH) agonists in prostate cancer https://www.prescqipp.info/our-resources/bulletins/bulletin-88-lhrh-analogues/

Appendix 1: Licensed indications for gonadorelin preparations[4]

Information correct at 21/04/2020. For the most up-to-date licensing information and dosing schedules please refer to each products' Summary of Product Characteristics (SmPC) available on the Electronic Medicines Compendium (eMC) (www.medicines.org.uk).

Drug	Goserelin		Leuprorelin		Triptorelin		
Product	**Zoladex 3.6mg Implant**	**Zoladex LA 10.8mg Implant**	**Prostap SR DCS (3.75mg)**	**Prostap 3 DCS (11.25mg)**	**Decapeptyl SR 3mg**	**Decapeptyl SR 11.25mg**	**Decapeptyl SR 22.5mg**
Administration interval	28 days	12 weeks	Monthly	3 monthly	28 days	3 monthly	6 monthly
Prostate cancer indications:							
Metastatic prostate cancer	✓	✓	✓	✓	✓	✓	✓
Locally advanced prostate cancer, as an alternative to surgical castration.	✓	✓	✓	✓	✓	✓	✓
Adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.	✓	✓	✓	✓	✓	✓	✓
Neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.	✓	✓	✓	✓	✓	✓	✓
Adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression.	✓	✓	✓	✓	✓	✓	✓
Breast cancer indications:							
Advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation.	✓		✓	✓			
Alternative to chemotherapy in the standard of care for pre/perimenopausal women with oestrogen receptor (ER) positive early breast cancer.	✓						
As adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in women at high risk of recurrence who are confirmed as pre-menopausal after completion of chemotherapy			✓ (recommended max. 5 years treatment)	✓ (recommended max. 5 years treatment)	✓ (recommended max. 5 years treatment)		
Preservation of ovarian function in pre-menopausal women with neoplastic disease undergoing chemotherapy treatment that can cause premature ovarian insufficiency.			✓				
Endometriosis:							
Treatment of endometriosis.					✓	✓	

					(max. 6 months treatment)	(max. 6 months treatment)	
Management of endometriosis, including pain relief and reduction of endometriotic lesions.	✓ (max. 6 months treatment)		✓ (max. 6 months treatment)	✓ (max. 6 months treatment)			
Endometrial thinning: Endometrial preparation prior to intrauterine surgical procedures including endometrial ablation or resection.	✓ (max. 8 weeks treatment) 4 or 8 weeks treatment		✓ (single dose 5-6 weeks prior to surgery)				
Uterine fibroids:							
Preoperative management of uterine fibroids to reduce their size and associated bleeding.			✓ (max. 6 months treatment)				
Treatment of uterine fibroids prior to surgery or when surgery is not appropriate.					✓(max. 6 months treatment)		
Uterine fibroids: In conjunction with iron therapy in the haematological improvement of anaemic patients with fibroids prior to surgery.	✓(max. 3 months treatment prior to surgery)						
Other indications – Specialist only outside scope of primary care							
Assisted reproduction: Pituitary downregulation in preparation for superovulation.	✓						
Treatment of precocious puberty (onset before 8 years in girls and 10 years in boys).						✓	
Treatment of central precocious puberty (CPP) in children 2 years and older with an onset of CPP before 8 years in girls and 10 years in boys).							✓
Treatment of central precocious puberty (girls under 9 years of age, boys under 10 years of age			✓(The administration interval should be 30 ± 2 days in order to prevent the recurrence of precocious puberty symptoms.)	✓(The administration interval should be 90 ± 2 days in order to prevent the recurrence of precocious puberty symptoms)			