Effective Shared Care Agreement (ESCA)

Opicapone ▼ capsules

ESCA: For adjunctive therapy in adult patients with Parkinson's disease and end-of-dose motor fluctuations who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy has been considered.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of opicapone capsules in Parkinson's disease can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Parkinson's disease are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of Parkinson's disease.
2. Confirm the patient has used entacapone (at maximum tolerated dose) and failed to respond to, OR has documentation of intolerance of, entacapone (excluding bodily fluids turning yellow), AND that apomorphine therapy has been considered.
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
5. Do baseline monitoring prior to initiation of opicapone capsules.
6. Initiate treatment and stabilise dose of opicapone capsules.
7. Retain prescribing responsibility for a minimum of 3 months to establish efficacy and patient benefit.
8. Review the patient's condition and monitor response to treatment regularly.
9. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
10. Report any suspected adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
11. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Ensure that the patient has used entacapone (at maximum tolerated dose) and failed to respond or has documentation of intolerance of, entacapone (this excludes bodily fluids turning yellow).						
3. Ensure that the specialist has prescribed entacapone for a minimum of 3 months and undertaken a successful review before transferring care.						
4. Prescribe opicapone capsules at the dose recommended by specialist.						
5. Adjust the dose as advised by the specialist.						
6. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
7. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
8. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment.						
9. Refer back to specialist if condition deteriorates.						
10. Report any suspected adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
11. Stop treatment on advice of specialist.						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with opicapone capsules with the specialist, clinical nurse specialist or GP
4. Report any adverse effects to the specialist or GP whilst taking opicapone capsules.
5. Attend regular outpatient appointments with the specialist

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Licensed indication	Indicated as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.	
BSSE APC agreed position	Second-line therapy to entacapone, in patients who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy has been considered.	
Dosage and Administration	The recommended dose of opicapone is 50 mg. Opicapone should be taken once-daily at bedtime at least one hour before or after levodopa combinations.	
Renal Impairment	No dose adjustment is necessary in patients with renal impairment, as opicapone is not excreted by the kidney	
Hepatic impairment	Mild (Child-Pugh Class A)	No dose adjustment is necessary in patients with mild hepatic impairment
	Moderate (Child-Pugh Class B)	There is limited clinical experience in patients with moderate hepatic impairment. Caution must be exercised in these patients and dose adjustment may be necessary
	Severe (Child-Pugh Class C)	There is no clinical experience in patients with severe hepatic impairment therefore, Opicapone is **not recommended** in these patients
Contra-indications	• Hypersensitivity to the active substance or to any of the excipients. • Phaeochromocytoma, paraganglioma, or other catecholamine secreting neoplasms. • History of neuroleptic malignant syndrome and/or non-traumatic rhabdomyolysis. • Concomitant use with monoamine oxidase (MAO-A and MAO-B) inhibitors (e.g. phenelzine, tranylcypromine and moclobemide) other than those for the treatment of Parkinson's disease	
Special precautions	<u>Dose adjustments of antiparkinsonian therapy</u> Opicapone is to be administered as an adjunct to levodopa treatment. Hence, the precautions valid for levodopa treatment should also be taken into account for opicapone. Opicapone enhances the effects of levodopa. To reduce levodopa-related dopaminergic adverse reactions (e.g. dyskinesia, hallucinations, nausea, vomiting and orthostatic hypotension), it is often necessary to adjust the daily dose of levodopa by extending the dosing intervals and/or reducing the amount of levodopa per dose within the first days to first weeks after initiating treatment with opicapone, according to the clinical condition of the patient. If Opicapone is discontinued it is necessary to adjust the dosing of the other antiparkinsonian treatments, especially levodopa, to achieve a sufficient level of control of the symptoms. <u>Psychiatric disorders</u> Patients and care-givers should be made aware that impulse control disorders including pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists and/or other dopaminergic treatments. Patients should be monitored regularly for the development of impulse control disorders and review of treatment is recommended if such symptoms develop. <u>Others</u> Increases in liver enzymes were reported in studies with nitrocatechol inhibitors of catechol-O-methyltransferase (COMT). For patients who experience progressive anorexia, asthenia and weight decrease within a relatively short period of time, a general medical evaluation including liver function should be considered. <u>Intolerance to excipients</u> Opicapone contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take opicapone.	
Side Effects	Very common	Dyskinesia
	Common	Abnormal dreams, hallucination, hallucination visual, insomnia, dizziness, headache, somnolence, orthostatic hypotension, constipation, dry mouth, vomiting, muscle spasms
Monitoring	Pre-treatment assessment	Liver function test Blood pressure and heart rate Psychiatric disorders - impulse control disorders
	After commencing treatment	Liver function test Blood pressure and heart rate Psychiatric disorders - impulse control disorders

Drug Interactions (significant interaction as outlined in BNF, please see BNF and SPC for more detail)

Opicapone has the following interaction information:

Agent	Severity of interaction	Evidence for interaction	Notes	Action
Adrenaline / epinephrine	Severe	Theoretical	Opicapone is predicted to increase the risk of cardiovascular side-effects when given with adrenaline/epinephrine.	
Dobutamine	Severe	Theoretical	Opicapone is predicted to increase the risk of cardiovascular side-effects when given with dobutamine.	
Dopamine	Severe	Theoretical	Opicapone is predicted to increase the risk of cardiovascular side-effects when given with dopamine.	
Isocarboxazid	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with isocarboxazid.	Manufacturer advises avoid.
Levodopa	Moderate	Study	Opicapone increases the exposure to levodopa.	Manufacturer advises adjust levodopa dose.
Moclobemide	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with moclobemide.	Manufacturer advises avoid.
Noradrenaline / norepinephrine	Severe	Theoretical	Opicapone is predicted to increase the risk of cardiovascular side-effects when given with noradrenaline/norepinephrine.	
Phenelzine	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with phenelzine.	Manufacturer advises avoid.
Rasagiline	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with rasagiline.	
Selegiline	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with selegiline.	
Tranylcypromine	Severe	Theoretical	Opicapone is predicted to increase the risk of elevated blood pressure when given with tranylcypromine.	Manufacturer advises avoid.

References

SmPC Ongentys® 50 mg hard capsules
BNF online (Oct 17) – Ongentys®
NICE Evidence summary [ES9] - Parkinson's disease with end-of-dose motor fluctuations: opicapone
NICE CG35 - Parkinson's disease in over 20s: diagnosis and management

Appendix 1:

Effective Shared Care Agreement (ESCA)

Opicapone▼ capsules

For adjunctive therapy in adult patients with Parkinson's disease and end-of-dose motor fluctuations who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy has been considered.

Please refer to BSSE APC formulary website for complete document.

To be completed by Specialist team

Confirm the patient	**Please tick**	**Dose of entacapone**
Has used entacapone (at maximum tolerated dose) and failed to respond	☐	
or		
Has documentation of intolerance of, entacapone (excluding bodily fluids turning yellow)	☐	
AND that		
Apomorphine therapy has been considered.	☐	

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with opicapone capsules as adjunctive therapy in adult patients with Parkinson's disease and end-of-dose motor fluctuations who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy has been considered.

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care