Indication	Adjuvant treatment for high risk hormone receptor-positive and HER2-negative early breast cancer. The patient may have received adjuvant or neo-adjuvant chemotherapy, but the patient should have received no more than 12 weeks of adjuvant endocrine therapy after completion of the last non-endocrine therapy (surgery or chemotherapy or radiotherapy). The patient should have had no prior treatment with a CDK 4/6 inhibitor unless the patient has suffered unacceptable toxicity on adjuvant ribociclib plus an aromatase inhibitor without any evidence of disease progression and is transferring to treatment with adjuvant abemaciclib plus endocrine therapy.
Treatment Intent	Adjuvant
Frequency and number of cycles	Every 28 days Until disease progression or excessive toxicity or until the patient chooses to discontinue treatment or for a maximum of 2 calendar years. NB for patients switching from ribociclib, the maximum total CDK4/6 inhibitor treatment duration is for 2 calendar years (time on ribociclib plus time on abemaciclib).
Monitoring parameters	• **Virology screening:** All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • Monitor **FBC, U&E** and **LFT** at baseline then at the beginning of each cycle for 6 months and then every 3 months thereafter or as clinically indicated. • If neuts >/= 1 and PLT >/= 100 proceed with treatment. • If neuts >/= 1 and PLT 76 to 99 give one month's supply of abemaciclib and inform consultant. • If neuts >/= 1 and PLT 50 to 75 withhold abemaciclib and discuss with consultant. • NB SPC recommendation; patients can receive abemaciclib if neuts >/=1 and PLT >/=50 • **Renal impairment:** No dose adjustment of abemaciclib is required for patients with mild or moderate renal impairment (CrCl >/=30 mL/min). Insufficient data are available in patients with severe renal impairment or those requiring haemodialysis to provide any dose adjustment recommendation, administer with caution. • **Hepatic impairment:** o **Abemaciclib:** No dose adjustment of abemaciclib is required for patients with mild or moderate hepatic impairment (Child-Pugh classes A and B). For patients with severe hepatic impairment (Child-Pugh class C), the dose frequency should be reduced to once daily. D/W consultant if bilirubin >2 x ULN. o **Letrozole** can be given in severe hepatic impairment, patients require close supervision. (see table 1 for management of increased aminotransferases) • If the patient is female they should either be post-menopausal, or if pre- or peri-menopausal and taking an aromatase inhibitor, should have undergone ovarian ablation or suppression with LHRH agonist treatment. • **Dose modification and toxicity guidance:** See tables 1 to 5 for management of toxicities. • **Dose reductions of abemaciclib**: 1st dose reduction to 100mg bd, 2nd dose reduction to 50mg bd. • **Management of diarrhoea:** Treat with loperamide. If grade 2 and toxicity does not resolve within 24 hours to grade 1 or less, suspend until resolution and restart at the same dose. For Grade 2 that persists or recurs after resuming the same dose or Grade 3 or 4 (or requires hospitalisation), suspend dose until toxicity resolves to Grade 1 or less and resume at next lower dose.

	• **Interstitial lung disease/pneumonitis:** Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis (e.g. hypoxia, cough, dyspnoea). • **Venous thromboembolism:** Patients should be monitored for signs and symptoms of deep vein thrombosis and pulmonary embolism and treated as medically appropriate. Based on the grade of VTE, abemaciclib may require dose modification. • **Common drug interactions (for comprehensive list refer to BNF/SPC) & food interactions:** o Concomitant use of strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin) should be avoided. If strong CYP3A4 inhibitors cannot be avoided, the abemaciclib dose should be reduced to 100 mg twice daily. In patients who have had their dose reduced to 100 mg abemaciclib twice daily and in whom co-administration of a strong CYP3A4 inhibitor cannot be avoided, the abemaciclib dose should be further reduced to 50 mg twice daily. In patients who have had their dose reduced to 50 mg abemaciclib twice daily and in whom co-administration of a strong CYP3A4 inhibitor cannot be avoided, the abemaciclib dose may be continued with close monitoring of signs of toxicity. Alternatively, the abemaciclib dose may be reduced to 50 mg once daily or discontinued. If the CYP3A4 inhibitor is discontinued, the abemaciclib dose should be increased to the dose used prior to the initiation of the CYP3A4 inhibitor (after 3 to 5 half-lives of the CYP3A4 inhibitor). o Concomitant use of abemaciclib with strong CYP3A4 inducers (carbamazepine, phenytoin, rifampicin, St John's Wort) should be avoided as it may lead to reduced exposure. o Caution with narrow therapeutic index substrates of P-gp and BCRP, such as digoxin or dabigatran etexilate. o Do not take with grapefruit or grapefruit juice. • **Missed dose**: If a patient vomits or misses a dose of abemaciclib, the patient should be instructed to take the next dose at its scheduled time; an additional dose should not be taken. • **Driving:** Patients should be advised to be cautious when driving or using machines in case they experience fatigue or dizziness during treatment with abemaciclib. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.
Reference(s)	SPC accessed on line 19.03.2026

NB for funding information, refer to CDF and NICE Drugs Funding List

Table 1. Management of increased aminotransferases

Toxicity	Management recommendations
Grade 1 (>ULN-3.0 x ULN) Grade 2 (>3.0-5.0 x ULN)	No dose adjustment required.
Persistent or Recurrent Grade 2, or Grade 3 (>5.0-20.0 x ULN)	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Elevation in AST and/or ALT >3 x ULN WITH total bilirubin >2 x ULN, in the absence of cholestasis	Discontinue abemaciclib.
Grade 4 (>20.0 x ULN)	Discontinue abemaciclib.

Table 2. Management recommendations for interstitial lung disease (ILD)/pneumonitis

Toxicity	**Management recommendations**
Grade 1 or 2	No dose adjustment required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures within 7 days to baseline or Grade 1	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Grade 3 or 4	Discontinue abemaciclib.

Table 3: Management recommendations for venous thromboembolic events (VTEs)

Toxicity	**Management recommendations**
Early Breast Cancer	
All Grades (1, 2, 3, or 4)	Assess and suspend dose if clinically indicated. Treat VTE as clinically indicated. Abemaciclib may be resumed when the patient is clinically stable.

Table 4. Management recommendations for non-haematological toxicities (excluding diarrhoea, increased aminotransferases, interstitial lung disease (ILD)/pneumonitis and VTE)

Toxicity	**Management recommendations**
Grade 1 or 2.	No dose adjustment required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures to baseline or Grade 1 within 7 days	Suspend dose until toxicity resolves to Grade 1 or less. Resume at next lower dose.
Grade 3 or 4	

Table 5 SPC recommendations for management of haematologic toxicities
NB see monitoring parameters for NOG guidance

Toxicity[a, b]	Management recommendations
Grade 1 or 2	No dose adjustment required.
Grade 3	Suspend dose until toxicity resolves to Grade 2 or less. Dose reduction is not required.
Grade 3, recurrent; or Grade 4	Suspend dose until toxicity resolves to Grade 2 or less. Resume at next lower dose.
Patient requires administration of blood cell growth factors	Suspend abemaciclib dose for at least 48 hours after the last dose of blood cell growth factors was administered and until toxicity resolves to Grade 2 or less. Resume at next lower dose unless the dose was already reduced for the toxicity that led to the use of the growth factor.

[a] NCI Common Terminology Criteria for Adverse Events (CTCAE)
[b] ANC: Grade 1: ANC < LLN – 1.5; Grade 2: ANC 1 - < 1.5; Grade 3: ANC 0.5 - < 1; Grade 4: ANC < 0.5
LLN = lower limit of normal

Cycle length - 28 days

TTO	Drug	Dose	Route	Directions
Day 1	**ABEMACICLIB**	**150mg**	PO	Twice DAILY for 28 days with or without food Swallow whole, do not chew or crush. Take the dose at approximately the same times each day. Do not take with grapefruit or grapefruit juice. This medicine may make you sleepy. If this happens, do not drive or use tools or machines. Available as 50mg, 100mg or 150mg tablets.
	LETROZOLE	**2.5mg**	PO	OD *An alternative endocrine therapy may be prescribed.*
	Loperamide	2-4mg	PO	Take 4mg (2 capsules) initially, then 2mg (1 capsule) after each loose stool when required. Maximum 16mg (8 capsules) a day. Dispense 30 capsules on cycle 1 then only if required.
	Metoclopramide	10mg	PO	10mg TDS PRN. Do not take for more than 5 days continuously. Dispense with cycle 1 then only if required.