### Summary of NICE TA 267

1. Ivabradine is recommended as an option for treating chronic heart failure for people:
   - with New York Heart Association (NYHA) class II to IV stable chronic heart failure with systolic dysfunction and
   - who are in sinus rhythm with a heart rate of 75 beats per minute (bpm) or more and
   - who are given ivabradine in combination with standard therapy including beta-blocker therapy, angiotensin-converting enzyme (ACE) inhibitors and aldosterone antagonists, or when beta-blocker therapy is contraindicated or not tolerated and
   - with a left ventricular ejection fraction of 35% or less.

2. Ivabradine should only be initiated after a stabilisation period of 4 weeks on optimised standard therapy with ACE inhibitors, beta-blockers and aldosterone antagonists.

3. Ivabradine should be initiated by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be carried out by a heart failure specialist or in primary care by either a GP with a special interest in heart failure or a heart failure specialist nurse.

### Number of people in Northern Ireland expected to take up service/therapy (new cases per year)

It is estimated that in total 346 people in Northern Ireland will be eligible for this treatment. It is expected that around 10% of this population will take up the treatment in the first year (=37 people).

It is anticipated that take up will increase by 10% of the total eligible population each year, so that by year 5 half of the eligible population will be on the treatment (=173).

### Costs

#### 3.1 Cost per patient per annum

**First year**

£210 administration cost of initiation plus cost of drug £507.20 = £717.20 for each new patient
Subsequent years

£507.20 for each patient remaining on treatment after first year.

There does not appear to be a rebate for this drug at the moment.

There may be additional costs as the SPC recommends monitoring in relation to this drug:

1. Monitor for renal and hepatic status.
2. Monitor for atrial fibrillation (sustained or paroxysmal), including ECG monitoring if clinically indicated (e.g. in exacerbated angina, palpitations, irregular pulse). The risk AF may be higher in chronic heart failure patients treated with ivabradine.
3. Monitor chronic heart failure patients with intraventricular conduction defects (bundle branch block left, bundle branch block right) and ventricular dyssynchrony closely.
4. Check pre-treatment resting heart rate: do not initiate in patients if below 60 beats per minute.
5. If, during treatment, resting heart rate decreases persistently below 50 bpm or the patient experiences symptoms related to bradycardia such as dizziness, fatigue or hypotension, titrate dose downward or stop treatment if heart rate below 50 bpm or symptoms of bradycardia persist.
6. Heart failure must be stable before considering ivabradine. Use with caution in heart failure patients with NYHA functional classification IV due to limited amount of data in this population.
7. Effects of long-term ivabradine treatment beyond one year on retinal function are currently not known. Consider stopping treatment if any unexpected deterioration in visual function occurs. Caution should be exercised in patients with retinitis pigmentosa.
8. Limited data available in patients with mild to moderate hypotension, and therefore use with caution in these patients.
9. Avoid in patients with congenital QT syndrome or treated with QT prolonging medicinal products. If the combination appears necessary, close cardiac monitoring is needed.
10. When treatment modifications are made in chronic heart failure patients treated with ivabradine blood pressure should be monitored at an appropriate interval.

Interacting drugs may also require monitoring. Please see SPC for full detail.

3.2 In year cost per patient per annum (for new and prevalent cases)

See Section 3.1 above.
3.3 Cost savings and how these will be secured

There are forecast savings in hospital admissions of £6k pa, total £30k over 5 years.

By year 5 it is estimated that there will be a drug cost of £105k.

Savings will accrue in secondary care whereas the majority of the costs (prescribing) will occur in primary care.

3.4 Recurrent overall cost

It is estimated that there will be savings from reduced admissions in secondary care of £6k per annum over 5 years increasing to £30k by year 5.

Drug and drug administration costs are expected to cost an additional £21k per annum increasing to £105k by year 5. The drugs costs are expected to be incurred in primary care.

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug and Admin £000's</th>
<th>Admissions Savings £000's</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2013-14</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>2014-15</td>
<td>(6)</td>
</tr>
<tr>
<td>3</td>
<td>2015-16</td>
<td>21</td>
</tr>
<tr>
<td>4</td>
<td>2016-17</td>
<td>(6)</td>
</tr>
<tr>
<td>5</td>
<td>2017-18</td>
<td>21</td>
</tr>
</tbody>
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105 (30)

4 Expected implementation period

Ready to implement.

5 Commissioning arrangements

Consideration will need to be given to the recommendation by NICE that it must be initiated by a specialist and monitored by those with special interest in heart failure (specialist /specialist GP / specialist nurse).

6 Monitoring arrangements

Monitoring of prescribing: volume, trend and prescriber (ivabradine should be initiated by a heart failure specialist). Dose titration and monitoring should be carried out by a heart failure specialist; or in primary care by either a GP with a special interest in heart failure or a heart failure specialist nurse.
DHSSPS Legislative/Policy Caveats

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.