NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

GID-HTE10007 Digitally enabled weight management programmes to support treatment with weight management medication

External Assessment Group Report Addendum 1

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Contains confidential information: Yes

Responsibility for report:
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Any 'commercial in confidence' information in the submission document (or corresponding appendices) are highlighted in turquoise.

Background of additional EAG work

During the evaluation of the technologies included within the Final Scope for 'GID-HTE10007 Digitally enabled technologies to support treatment with weight-management medication in specialist-weight management services: early value assessment', no published evidence relating to one of the technologies (Juniper) was identified by the EAG searches (conducted May 2023), nor was any information

provided by the Company. During public consultation for the topic, Juniper submitted evidence in confidence for consideration by the Committee. The Newcastle EAG have summarised the evidence submitted, including details relating to the technology.

Summary of the technology

Juniper is a web-based platform available on computers and as a smartphone app. Patients can access educational content, communicate with professionals from the Juniper multidisciplinary team (MDT) and record data. Data collected in the platform includes self-reported measurements of weight, waist circumference, eating habits, sleep, water consumption, medication (use and dose) and mood. The technology uses an algorithm to flag patients who may require MDT support.

Accessibility and equality

Juniper is currently only available in English for the UK market. Further multi-language capability is planned as part of the EQuIP6 accreditation quality improvement program. The technology currently supports larger text sizes and alternate text for all sections of the app that are interactable, for example, hyperlinks, and buttons, which may be compatible with screen readers. However, the Company's RFI response notes that the technology is not suitable for visually impaired or blind patients. No further detail was provided relating to accessibility for people with learning disabilities, non-English speakers, or other groups.

Regulatory status

Juniper is not currently CE or UKCA marked as the Company note that the platform is a "decision support tool" for practitioners rather than a medical device. An application for assessment against the Digital Technology Assessment Criteria (DTAC) is planned for December 2023.

Referrals and integration into the NHS

Currently, access to Juniper is restricted to private services sought by the public (self-referral). Juniper is not currently being used within the NHS. The Company report that their service is accessible to patients throughout the UK, regardless of their eligibility for NHS services.

MDT staff and frequency of reviews

The MDT communicates daily and meets regularly (frequency not provided) to discuss patient safety events, incidents and other areas or issues within the clinical governance framework. The MDT has clinical governance over weight management, although can collaborate with the patient's regular GP or specialist if required.

The UK MDT comprises pharmacist-independent prescribers, registered pharmacists, dispensing pharmacists, dietitians, clinical nutritionists, and health coaches. Juniper advise that they are currently seeking to recruit a psychologist, physical activity specialists, and a physiotherapist.

In-house prescribing and adherence monitoring

Juniper includes in-house prescribing of weight loss medication for suitable patients in the UK by Pharmacist Independent Prescribers (PIPs) (GPhC registered) who prescribe and manage a patient's treatment.

Juniper has integral decision support in the platform to identify clinical flags with the prescriber before a prescribing action has been confirmed. Prescription plans are for a maximum of 6 months treatment before mandatory routine review. There is continual access to the platform if a person wishes to raise an issue, and response is given within 24 hours (personnel and method unspecified). If patients require a follow up consultation before 6 months due to side effects or clinical queries the treatment is placed on hold until consultation with a member of the clinical team.

Juniper report that patients have fortnightly check-ins to track weight and raise concerns about side effects, however do not include detail for how this is conducted (such as, via telephone, virtual messaging, video calls, or whether communication is in real time or asynchronous). Patients can raise concerns to a dedicated health coach who is trained to escalate matters to an appropriate member of the MDT. The platform includes a 'Trends Engine' which tracks "Active" data submitted by the patient or member of the MDT, such as medication adherence. 'Passive' data is also logged by internal systems accessed by MDT members, including monthly dosage information.

Adverse events

See Section 6 of the EAG report for previous safety searches conducted by the EAG. The Company report that adverse events are captured from patient-reported data relating to side effects, either directly in the app or to a member of the MDT. Juniper advises that they have policies to identify and manage high-risk patients, including specific protocols and MDT training for eating disorders and mental health, and escalation or sign-posting to external services where appropriate. The Company report a 'verification process' to prevent medication misuse, however provide no additional details. A clinical analytics query is run every 48 to 72 hours comparing clinical patient information against clinical events.

Training

When patients join the platform there are several resources, which include an onboarding education module addressing programme overview and first-dose support videos. There is a self-service training library accessible throughout the programme.

All members of the MDT receive an individual compulsory technology onboarding by members of the Juniper team, including clinical training by the leads for each MDT field and clinical governance processes, which are overseen by a global advisory board. Clinical audits on all members of the MDT are continuous with quarterly performance reviews. This includes aspects such as the rate at which patient suitability is determined and first response time connecting with patients.

Bariatric surgery

Juniper do not currently record data relating to progression to bariatric surgery, however do collect data for patients who have undergone previous weight loss surgery prior to undertaking the programme.

Summary of evidence

Juniper provided details of 3 ongoing or planned studies (Table 1), including 2 with interim data (Table 2):

- **Study 1 (Juniper CiC-1):** [redacted]

[redacted]

Study 2 (Juniper CiC-2): [redacted]

Study 3 (Juniper CiC-3): [redacted]

The inclusion criteria and baseline characteristics of the population were poorly reported, however the EAG has assumed all patients are eligible for weight loss medication as part of the eligibility to the medication-assisted programme and note that the mean baseline BMI is above 30 kg/m2 where reported. Interim follow-up data is available up to 11 months although the number of participants at each follow-up time point is not reported.

Key findings from interim data

Weight loss

[redacted]

Adverse events

[redacted]

Retention and Adherence

[redacted]

Satisfaction

[redacted]

Key findings summary

All the evidence relating to Juniper includes patients taking concomitant weight loss medication, which is in line with the Final Scope. [redacted]

[redacted]

he EAG consider the existing summary of the evidence gaps and recommendations for evidence generation reported in Sections 8.4 to 8.6 of the EAG report would also be applicable to Juniper.

Table 1: Summary of ongoing studies for Juniper (N=3)

Study title [ref]	Study design (number of patients); [estimated completion date] Country	Population	Intervention	Comparator	Intermediate measures: Engagement with the programme	Intermediate measures: Intervention adherence, attrition, completion	Intermediate measures: Intervention-related adverse events	Intermediate measures: Weight management medication adherence	Intermediate measures: Inaccessibility to intervention	Clinical outcomes: BMI	Clinical outcomes: Weight loss	Clinical outcomes: Body fat	Clinical outcomes: Waist circumference	Clinical outcomes: Hip circumference	Clinical outcomes: Waist-to-hip ratio	Clinical outcomes: Glycated haemoglobin (HbA1c)	Clinical outcomes: Cardiovascular events	Clinical outcomes: Mortality	Clinical outcomes: Physical activity	Clinical outcomes: Rate of referral for weight loss surgery	Clinical outcomes: Eating habits	PROMs: Patient reported outcomes	PROMs: Satisfaction	Health resource use: Healthcare appointments	Health resource use: Medication use	Health resource use: Healthcare professional grade and time
Juniper CiC-1: [redacted]	[redacted]	**GREEN**	**GREEN**	N/A			✓			✓	✓												✓			
Juniper CiC-2: [redacted]	[redacted]	**GREEN**	**GREEN**	N/A			✓			✓	✓												✓			
Juniper CiC-3: [redacted]	[redacted]	NR	**GREEN** (Juniper and semaglutide vs Juniper, semaglutide and strength training)	**GREEN** (in-person weight management and semaglutide)		✓	✓				✓															

Key: **GREEN** aspect of study in scope
Abbreviations: N/A, not applicable; NR, not reported; vs, versus

Table 2: Summary of ongoing studies with interim results (N=2)

#	Study (year) [design, n]	Population	Intervention and comparator	Key results	EAG Comments
1.	Juniper CiC-1: [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2.	Juniper CiC-2: [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: N/A, not applicable; NR, not reported

Table 3: Evidence Gap Analysis for Juniper

Outcome measure		Juniper (N=2)
Intermediate measures	Engagement with the programme	**RED** None
	Intervention adherence, rates of attrition and completion	**AMBER** Juniper CiC-1, Juniper CiC-2
	Intervention-related adverse events	**RED** None
	Weight management medication adherence and medication-related adverse events	**AMBER** Juniper CiC-1, Juniper CiC-2
	Inaccessibility to intervention (digital inequalities)	**RED** None
Clinical outcomes	BMI	**AMBER** Juniper CiC-1, Juniper CiC-2
	Weight loss	**AMBER** Juniper CiC-1, Juniper CiC-2
	Body fat	**RED** None
	Waist circumference	**RED** None
	Waist-to-hip ratio	**RED** None
	Hip circumference	**RED** None
	HbA1c	**RED** None
	Cardiovascular events	**RED** None
	Mortality	**RED** None
	Physical activity	**RED** None
	Rate of referral for weight loss surgery	**RED** None
	Eating habits	**RED** None
PROMs	Health-related quality of life	**RED** None
	Patient satisfaction	**AMBER** Juniper CiC-1, Juniper CiC-2
Economics	Healthcare appointments	**RED** None
	Medication use and adverse events	**AMBER** Juniper CiC-1, Juniper CiC-2
	Healthcare professional grade and time	**RED** None

Summary of economic considerations

Cost of the technology

The Company provided a cost of Juniper as £45 per month exclusive of VAT and weight loss medication. The monthly subscription includes digital Bluetooth scales.

EAG economic modelling

Early economic modelling was undertaken by the EAG as part of this EVA, please see Section 7 of the EAG report.

The EAG have not conducted any additional modelling specific to Juniper. The EAG note that no quality of life outcomes were reported in the evidence that would enable the EAG to derive utilities and QALYs for modelling. The EAG would also highlight that the cost of the technology is comparable to the range of costs of the other technologies in Scope of this evaluation so may plausibly be cost-effective if the range of outcomes included in the modelling can be generalised to Juniper.