

# 10 Harley Street

## Inspection report

10 Harley Street  
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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

### Ratings

Overall rating for this location		Requires Improvement	
Are services safe?	Good	Good	
Are services effective?	Requires Improvement	Requires Improvement	
Are services caring?	Good	Good	
Are services responsive to people's needs?	Good	Good	
Are services well-led?	Requires Improvement	Requires Improvement	

# Overall summary

**This service is rated as Requires improvement overall.** (Previous inspection in July 2022 – Inadequate).

The key questions are rated as:

Are services safe? – Good

Are services effective? – Requires improvement

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection at 10 Harley Street to follow up breaches of regulations from the July 2022 inspection. When we inspected the service in July 2022, we asked the provider to make improvements following breaches of regulations and we issued a Warning Notice under Section 29 of the Health and Social Care Act 2008 for Regulation 17, good governance. Requirement Notices were also issued for Regulation 12, safe care and treatment and Regulation 18, staffing. We checked these areas as part of this comprehensive inspection and found most of the breaches identified had been resolved and significant improvement had been made in providing safe care to patients; however, we continued to find gaps in the effective care of patients and in relation to governance.

There is a registered manager in place. A registered manager is a person who is registered with the Care Quality Commission (CQC) to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Botonics Limited, 10 Harley Street is an independent provider and is registered with the CQC to provide diagnostic and screening procedures, surgical procedures and treatment of disease, disorder or injury in relation to cosmetic treatments where there are some exemptions from regulation by CQC. These relate to particular types of regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The provider also provides a separate aesthetics service delivered by a clinician working in the service. This included full facial rejuvenation and anti-ageing treatments. These types of arrangements are not within CQC scope of registration; therefore, we did not inspect or report on these services.

There were no comment cards distributed to patients as part of this inspection and no patient interviews were carried out during the inspection. Patient feedback was found on Trustpilot online and google reviews.

## Our key findings were:

- The provider had taken steps to ensure Isotretinoin prescribing doctors at the service were now part of a consultant led team.
- The provider checked and verified the identity patients using their services in accordance with GMC guidelines.
- There was now a named safeguarding lead and a safeguarding policy in the service.
- Indemnity arrangements were in place for the service.

# Overall summary

- There was now a process in place to log, discuss, share and action safety alerts.
- The provider obtained consent prior to providing care and treatment.
- Online patient feedback showed significantly high numbers of positive patient satisfaction with the service.
- Staff felt respected and valued.
- The provider did not always assess needs and deliver care and treatment in line with current legislation, standards and guidance.
- There were gaps in governance arrangements.
- Processes for managing risks, issues and performance were not always clear or effective

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.
- Ensure staff receive training relevant to their role.

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

- Continue with quality improvement activity.
- Review and act on the recent national recommendations in relation to notifying the GP when a patient commences treatment with Isotretinoin.
- Review national guidance in relation to first consultations being carried out face to face wherever possible.
- Take action to provide a google translate option on the provider website.
- Share business contingency plan with all staff.

**Dr Sean O’Kelly BSc MB ChB MSc DCH FRCA**

Chief Inspector of Healthcare

## Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a GP specialist advisor and a member of the CQC medicines team.

## Background to 10 Harley Street

Botonics Limited is located at 10 Harley Street, W1G 9PF, in the London Borough of Westminster. The registered manager operates the service full time from the headquarters and administration offices of Pump House, Plumtree Cross Lane, Itchingfield, Horsham, Sussex, RH13 0NN which is no longer registered with CQC. The provider applied to remove this address as their registered location with CQC in March 2020, as it was not a clinical location to carry out any regulated activities.

Services provided include dermatology, body treatments and plastic surgery. Isotretinoin treatment (a high-risk medicine used to treat severe acne) is provided by two General Medical Council (GMC) registered doctors who provide a combined total of 6.5 hours at the service. Also employed are a registered mental health nurse and another GP. The provider recently recruited a dermatologist on the General Medical Council (GMC) specialist register i.e. consultant dermatologist.

At the time of inspection and since the Covid-19 pandemic, all services related to Isotretinoin prescribing (used to treat severe acne) continued to be provided fully online; for example, GPs carried out online consultations remotely; usually from their home. The management staff for the organisation were based in the offices of Horsham and two administration staff were based overseas in the Philippines.

The provider has a service level agreement with 10 Harley Street to hire a consultation room for their aesthetics service; Room 11 twice a week on Wednesday between 1:30pm and 5.30pm and Friday between 1:30pm and 5.30pm. The location rooms were used for aesthetic services which were out of CQC scope of regulation and not assessed as part of the inspection.

The service is open between 9.00am and 5.00pm on Monday to Friday. The provider also provides telephone and email support seven days a week and hours vary between 10.00am and 7.00pm at the weekends and between 5.00am and 11.00pm on some weekdays. The provider's website can be accessed at [www.botonics.co.uk](http://www.botonics.co.uk).

Botonics Limited also has a service level agreement with a separate partner company that is based in Harley Street for the use of surgical theatre facilities. The separate location was not a condition of the provider's registration and the service level agreement allows Surgical Procedures to be carried out by it.

The provider also operates another brand known as Treatdirect, non-limited company which operates the same governance systems as Botonics Limited and provides the same prescribing clinicians as Botonics Limited. This company was not visited as part of this inspection.

### How we inspected this service

Before the inspection, we reviewed a range of information regarding the service, including their action plan submitted following the previous inspection. The inspection was carried out remotely via Teams and we interviewed staff and reviewed documents.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

# Are services safe?

At the last inspection we found:

- The provider did not have a safeguarding policy and lead in the service to manage safeguarding processes.
- Staff did not always have the information they needed to deliver safe care and treatment to patients.
- The prescribing systems in place were not safely managed.
- The arrangements in place for making improvements when things went wrong and learning required improvement.
- The provider could not demonstrate they had a safe or effective system in place for verifying the identity of patients using their services.

At this inspection, significant improvements had been made. We found:

- The provider had met the requirements of the General Medical Council (GMC) and the Medicines and Healthcare products Regulatory Agency (MHRA), as a consultant dermatologist with expertise in the use of systemic retinoids was now in post since May 2023, to supervise the service's GMC registered doctors in prescribing Isotretinoin.
- A named safeguarding lead and policy was now in place.
- The provider could demonstrate they had a safe or effective system in place for verifying the identity of patients using the service.
- The consultant dermatologist had carried out the first prescribing audit.
- The provider had the appropriate indemnity arrangements in place.
- The practice now had processes in place to log, share and discuss patient safety alerts.

We identified a safety concern that was rectified soon after our inspection. At the previous inspection we found the provider could not demonstrate that the clinicians signing prescriptions had undergone appropriate training, or ensure their prescribing was carried out under a consultant led team. At this inspection we found although a consultant dermatologist was now in post, they had not reviewed the prescribing of the clinicians and therefore, could not meet the requirements of the Warning Notice to ensure clinicians prescribing this medicine were doing so under the supervision of consultant dermatologist. During the inspection process, the consultant provided assurances by carrying out a review of the clinicians records and updated the Isotretinoin prescribing policy. Due to the consultant dermatologist now in post and having carried out the initial audit of the prescribing doctors consultations, the likelihood of this happening again in the future is low and therefore our concerns for patients using the service, in terms of the quality and safety of clinical care are minor. (see full details of the action we asked the provider to take in the Requirement Notices at the end of this report).

However, there continued to be some gaps with regards to training. For example, we found:

- There were gaps in training such as, health and safety and information governance or data protection for some staff.

## Safety systems and processes

### The service had improved their systems to keep people safe and safeguarded from abuse.

- The Registered Manager advised they did not generally provide any treatment to children under the age of 18, unless in unusual cases when their condition was severe; however, this would be carried out with the parent or guardian present. As of 26 July 2023, following discussion with the consultant dermatologist, the provider told us patients under 18 years of age would no longer be treated by the service.

# Are services safe?

- The registered manager was now the named safeguarding lead and this was documented in the safeguarding policy. The provider told us staff knew how to identify and report concerns. We saw evidence that the registered manager, consultant dermatologist and the prescribing clinicians were up to date with their level three safeguarding training appropriate to their role.
- The provider had a process in place to verify the identity of patients using their service in accordance with GMC guidelines. Patient identification was now required on registration, or before offering treatment and this was uploaded on their file.
- The service had processes in place to work with other agencies such as the local authority to support patients and protect them from neglect and abuse. They had a safeguarding policy in place that was last reviewed in March 2022 and contained information regarding the local authority's safeguarding team.
- The provider told us they carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required; they provided evidence of a DBS check for the newly recruited consultant dermatologist and for the prescribing clinicians. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).
- The provider expected that all GPs would conduct consultations in private and maintain the patient's confidentiality. Each GP used an encrypted, password secure laptop to log into the operating system, which was a secure programme.

## Risks to patients

**There were systems to assess, monitor and manage risks to patient safety; however, monitoring was required to ensure staff received the appropriate training.**

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an induction system for staff tailored to their role.
- Staff we spoke to understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. They knew how to identify and manage patients with severe infections, for example sepsis. However, we found gaps in sepsis training for staff; for example, at the time of inspection only one of the two prescribing clinicians had completed their sepsis training. After the inspection, the provider sent evidence of completed sepsis training for the second clinician.
- The provider had the appropriate indemnity arrangements in place. We saw evidence of an up to date certificate of employers liability insurance.

## Information to deliver safe care and treatment

**Staff had the information they needed to deliver safe care and treatment to patients.**

- The provider had systems for sharing information with staff to enable them to deliver safe care and treatment.
- Individual care records were safely locked away. Although the registered manager sent evidence of their information governance training, including for administration staff based overseas, there was no evidence to show all clinical staff had received up to date information governance or data protection training. For example, one clinician last received this training in 2016.

# Are services safe?

- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. The provider continued to use their own tailor-made tracker system for the prescribing of Isotretinoin. We observed each clinician had their own patient tracker spreadsheet which was easy to read and contained patient information including weight measurements, blood tests and dates relating to course of treatment.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

## Safe and appropriate use of medicines

### The service had reliable systems for appropriate and safe handling of medicines.

- There was a prescribing policy in place which was reviewed and approved by the consultant dermatologist in July 2023, to ensure prescribing was in line with national guidance.
- Prior to the inspection, there was no regular auditing of Isotretinoin to ensure prescribing was in line with best practice guidelines for safe prescribing. However, the provider told us as the consultant dermatologist had plans to audit 1% of the patient records. During the inspection, the consultant dermatologist carried out their first prescribing audit for the service and made recommendations such as, establishing a more streamlined process of uploading patients photo identification and recording date of appointments clearly on the patient records. They also agreed on an action plan with the provider to carry out quarterly audits on 1% of the patient records to assess whether their care has complied with the Botonics Isotretinoin Policies and Procedure, recently updated by the consultant dermatologist.
- The provider told us normal treatment was often 6 months in duration and patients had the option to extend their treatment for a further month if they had not reached their treatment objectives.
- The provider told us prescriptions were authorised online by the doctors and they worked closely with one particular pharmacy that dispensed their prescriptions directly to the patients using an e-pharmacy system.

## Lessons learned and improvements made

### The service learned and made improvements when things went wrong.

- The provider told us they had a system for recording and acting on significant events; however, we were not provided with any examples of significant events at this inspection as the provider told us there had not been any since the last inspection.
- Staff understood their duty to raise concerns and report incidents and near misses. Leaders supported them when they did so.
- There were systems for reviewing and investigating when things went wrong. The service told us they learned and shared lessons identified themes and took action to improve safety in the service.
- The provider was aware of the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty and there was a detailed policy in place.

### When there were unexpected or unintended safety incidents:

- The service had an effective mechanism in place to receive and disseminate patient safety alerts to all members of the team.
- Since the last inspection they signed up to the Central Alerts System (CAS) and MHRA alerts and they were receiving daily alerts. The provider discussed an example of an alert received in April 2023 relating to Isotretinoin prescribing guidelines and clinicians we spoke to described how alerts were disseminated to them.

# Are services effective?

At the last inspection we found:

- We were not assured the provider always assessed needs and delivered care and treatment in line with current legislation, standards and guidance relevant to their service.
- The service was not actively involved in quality improvement activity.
- Staff did not have the right specialist skills, knowledge and experience to carry out their roles.

At this inspection, we rated effective as Requires improvement because:

- Meetings were now taking place and we saw documented evidence of this.
- Initial consultations were not being held face to face as per national guidance.
- The provider did not always assess needs and deliver care and treatment in line with current legislation, standards and guidance. However, the newly recruited consultant dermatologist had created a joint action plan with the provider to supervise the prescribing clinicians and ensure the prescribing policies were in line with all national guidelines.

## Effective needs assessment, care and treatment

### The provider had systems to keep clinicians up to date with current evidence-based practice.

- The provider told us the service doctors used a WhatsApp messaging group where they shared information and learning regarding Isotretinoin prescribing.
- The service held virtual meetings every three months which were minuted. The provider told us that since the last inspection, meetings were held in January, April and due in July 2023. We saw evidence of meeting minutes held in July 2023.
- The consultant dermatologist's role also included ensuring clinicians were up to date with current evidence-based practice, by reviewing all prescribing related documents to ensure they adhered to national guidelines such as the British National Formulary (BNF) and other nationally published resources, including the National Institute for Health and Care Excellence (NICE) guidance.

### The provider did not always assess needs and delivered care and treatment in line with current legislation, standards and guidance relevant to their service.

- The provider had improved some of their systems to assess needs and deliver care in line with relevant and current evidence-based guidance; however, this was not consistent overall. At the time of inspection, the provider was carrying out 20-25 consultations a month, which they told us had reduced since the last inspection.
- On inspection, we reviewed 10 random patient records and found although prescribing had improved in some areas; however, other areas showed they did not always prescribe Isotretinoin according to evidence-based guidance. For example, at the last inspection we found there was no evidence of pregnancy tests for 2 of the 9 eligible patient records we reviewed. At this inspection, this had improved and we found evidence that all 6 of the 10 eligible patient records we reviewed had evidence of a pregnancy test prior to authorisation of treatment and monthly, even if contraception was used and this was in line with national guidance.
- We also found information regarding side-effects of Isotretinoin were discussed with patients prior to commencing treatment and on inspection we found all 10 patients were monitored for side effects as per national guidance.



# Are services effective?

- However, we continued to find the initial consultations were not being carried out face to face wherever possible, as per the MHRA guidance around first consultations. The provider told us all their consultations for Isotretinoin prescribing were fully online for patients all over the United Kingdom and this was because they did not want to prejudice those living close by with those living further away, hence they wanted to have the broadest geographical reach. Clinicians we spoke to discussed that local patients had the option of attending their appointments face to face at their 10 Harley Street location although there was no uptake for this. However, this rationale was not in line with national guidance that gave an exception for patients at risk of Covid-19 infection.
- We continued to find gaps around the assessment of patients mental wellbeing prior to prescribing this medicine. The provider had insufficient systems in place to mitigate the mental health risks associated with Isotretinoin prescribing; for example, there was no formal mental health questionnaire completed prior to prescribing and doctors we spoke to told us they used their own mental health questionnaire they obtained from the NHS. The prescribing policy in place did not record information regarding completing the appropriate mental health questionnaire prior to prescribing. On inspection we found 1 of the 10 patients was prescribed a mental health related medicine, although the indication was unknown and a second patient had declared a history of mental health conditions five years prior and on active treatment. However, there was no evidence that an appropriate psychiatric evaluation by a psychiatrist had been conducted on these patients prior to prescribing Isotretinoin, or that the recommended standard mental health screening tool had been implemented prior to prescribing as per recommended guidelines. Particular care needs to be taken in patients with a history of depression and the risk of psychiatric disorders for each patient should be considered as part of the benefit-risk assessment at the initial prescribing appointment and during each follow-up appointment.
- We also found 8 out of 10 patient records we reviewed suggested that patients had slightly elevated cholesterol levels and we were not provided with any further information on how these patients were further monitored or evidence of interaction with their NHS GP when blood test results were outside of normal ranges. According to their prescribing tracker, these patients were still due to continue treatment, or had completed it. This placed them at risk of harm as elevated cholesterol levels are a contraindication of this medicine.
- We also found for 7 of the 10 patients who had more than one blood test, this was done at an interval of more than 1 month apart from when they started treatment with Isotretinoin with the provider. The BNF guidance stated when monitoring patient parameters for Isotretinoin to measure their hepatic function and serum lipids before treatment, 1 month after starting and then every 3 months and to reduce dose or discontinue if transaminase or serum lipids persistently raised. When we discussed our findings with the consultant dermatologist and the provider, they agreed guidance was not being followed in these areas. Following our findings, they acted to rectify the issues. For example, the consultant dermatologist immediately amended their Isotretinoin policies and procedures to reflect and ensure the assessment and provision of care would be delivered according to the national guidelines.
- As part of their ongoing treatment, the service told patients to take monthly pictures of their skin condition for the duration of their treatment to monitor progress.
- We saw no evidence of discrimination when making care and treatment decisions.

## Monitoring care and treatment

**There was some evidence of quality improvement activity, although this required embedding into the service.**

- The service made some improvements through the use of completed audits. At the time of inspection, there was no regular auditing of Isotretinoin to ensure prescribing was in line with best practice guidelines for safe prescribing.

# Are services effective?

However, the new consultant dermatologist carried out their first prescribing audit during the inspection and made the appropriate recommendations. For example, following the audit they found patient documentation required streamlining to enable easy review of information and date of patient appointments was not clear on the patient tracker. The service scheduled to undertake quarterly Isotretinoin prescribing audits.

- Patients were sent a feedback form following their treatment so the service could improve the quality of their service.
- There were no other audits such as prescribing antibiotics and note keeping audits carried out at the time of inspection.

## Effective staffing

**Staff had the skills, knowledge and experience to carry out their roles; however, monitoring was required to ensure supervision was taking place.**

- There is no legislative requirement for Isotretinoin to be prescribed by a dermatologist on the specialist register (consultant dermatologist) at the GMC; however, the MHRA guidelines state Isotretinoin is to be prescribed by, or under supervision of consultant dermatologists who have expertise in the use of systemic retinoids. Guidelines also state that it is not illegal for a GMC registered prescriber to prescribe Isotretinoin as long as adequate safeguards were in place. At the last inspection in 2022, we were not assured of adequate safeguards in place about the prescribing of the medicine Isotretinoin as prescribing was not carried out under a consultant led team and prescriptions were not issued under the consultant's name and although the service had registered General Medical Council (GMC) doctors, there were no consultant dermatologists working in the service to prescribe Isotretinoin as per national guidelines. Two of the GPs prescribed Isotretinoin for the service, some of which held a junior doctor post. Therefore, the provider could not demonstrate that the clinicians signing the prescriptions had undergone appropriate training, or that they had the scope of practice congruent with the prescribing of this high-risk medicine.
- However, we found at this inspection the provider had recruited a consultant dermatologist in May 2023 whose role was to supervise the prescribing GMC registered doctors at the service. The consultant dermatologist, who had extensive dermatology knowledge and experience, was on the GMC specialist register and had expertise in the prescribing of Isotretinoin and a complete understanding of the risks of therapy and monitoring requirements.
- The provider submitted evidence to show the consultant dermatologist had reviewed and signed off their Isotretinoin prescribing policy in July 2023; however, they had not yet undertaken formal review of the prescribing doctors.
- At the last inspection we found the provider website misleading in relation to stating that consultations were with a cosmetic dermatology specialist. The provider website also stated consultations and check-ups were carried out by GMC registered specialist doctors and although the doctors were indeed registered with the GMC, they were not on any specialist register. At this inspection we found the website terminology had changed and the doctors were now referred to as experts in cosmetic dermatology.
- There was a registered mental health nurse working in the aesthetic services which were out of CQC scope of regulation and not assessed as part of the inspection.
- At the time of inspection, there were gaps in mandatory training such as sepsis training. The provider told us staff received annual appraisals and clinicians we spoke to also received annual NHS appraisals and were up to date with their revalidation. We were provided with appraisal records for both prescribing clinicians.
- The registered manager provided evidence to show their information governance, health and safety and equality and diversity training was up to date. We saw evidence that all staff had completed equality and diversity training, as well as up to date information governance training, except for one clinician who last completed this training in 2016.

# Are services effective?

- There were no health and safety training records provided for four remote working clinical and non-clinical staff.

## **Coordinating patient care and information sharing**

### **The processes to ensure staff worked well with other organisations, to deliver effective care and treatment were not always demonstrated.**

- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. We saw examples of patients being signposted to more suitable sources of treatment where this information was not available to ensure safe care and treatment.
- The provider encouraged patients to notify their GP of their treatment, so they could update their system. The provider would obtain consent from patients first to notify their GP of their Isotretinoin treatment which included their treatment summary details and blood test results, which was often by email from the practice. We saw evidence of this system where patients were informed that Isotretinoin was a powerful medicine which could interact with other treatments. They told us GPs were not informed if patients did not provide consent and at least 25% of patients consented to their GP being informed of their treatment. .
- On inspection, all 10 patient records we reviewed did not consent to their treatment being shared by the GP and 2 of these patients had history of mental health conditions or treatment. Following The Commission on Human Medicines (CHM) and its Isotretinoin Expert Working Group (IEWG) report published in October 2023, the recommendations were that there should be clear communication from dermatology services to general practice that a patient has started treatment with isotretinoin. Emphasis was placed on clear communications notifying all involved healthcare professionals of any problems experienced by the patient.
- We saw examples where treatment was coordinated with other services; for example, clinicians told us some patients were referred to them from other practitioners such as, laser specialists for acne.
- Patient information was shared appropriately and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.

## **Supporting patients to live healthier lives.**

### **Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.**

- Where appropriate, staff gave people advice so they could self-care. This included provision of a product information brochure on the type of medicine and potential side effects and information regarding how they measured their own weight prior to treatment.
- Where patients' needs could not be met by the service, staff redirected them to the appropriate service for their needs.

## **Consent to care and treatment**

### **The provider obtained consent to care and treatment in line with legislation and guidance.**

- Staff understood the requirements of legislation and guidance when considering consent and decision making.

# Are services effective?

- The provider told us consent forms were completed prior to treatment. Patients were sent Isotretinoin treatment information and Isotretinoin patient product information brochures, which included potential side effects, prior to their first consultation so they could provide informed consent. We saw evidence of a signed, comprehensive consent form that contained information including the Isotretinoin pregnancy prevention programme which highlighted the risks of severe birth defects during pregnancy.
- Staff supported patients to make decisions.

# Are services caring?

We rated caring as Good because:

- Staff treated patients with kindness, respect and compassion.
- Online feedback relating to patient experience was significantly positive.
- Patient's privacy and dignity was respected.

## **Kindness, respect and compassion**

### **Staff treated patients with kindness, respect and compassion.**

- The service sought feedback on the quality of clinical care patients received, although we were not provided with evidence of a feedback questionnaire example on request.
- The service gave patients timely support and information.
- We did not speak to patients directly during inspection but online feedback from patients was positive about the way staff treat people. Patients were asked to provide feedback after consultation and we saw the service was rated 5-stars out of 501 reviews on Trustpilot. Patients were complementary about the treatment they received. The service was also rated 4.9-stars out of 60 reviews on Google, with only 1 negative review received in the past year which the provider told us they had attempted to respond to.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.

## **Involvement in decisions about care and treatment**

### **Staff helped help patients to be involved in decisions about care and treatment; however, translation arrangements were required.**

- The practice used interpretation services for patients who did not have English as a first language; however, there was no language translate option observed on their website.
- Staff communicated with people in a way that they could understand, for example, patients could communicate via email if that was preferred. We observed the website had a 'get in touch' form that patients could complete to contact the provider.

## **Privacy and Dignity**

### **The service respected patients' privacy and dignity.**

- Staff recognised the importance of people's dignity and respect, especially when patients using the service were experiencing issues with confidence due to their skin condition.

# Are services responsive to people's needs?

We rated responsive as Good because:

- The service organised and delivered services to meet patients' needs.
- Patients were able to access care and treatment from the service within an appropriate timescale for their needs. Online patient feedback was overwhelmingly positive about the way the service met patients' needs.
- The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

## Responding to and meeting people's needs

**The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.**

- The provider understood the needs of their patients and improved services in response to those needs. The service aimed to provide efficient treatment to patients who were often expressed issues with self-confidence as a result of their condition which was exacerbated by lengthy waits for this treatment on the NHS. They also told us patients preferred their online service as the treatment was accessible to them in whatever part of the country they resided and this was consistent with online feedback we reviewed, where patients described the service as offering bespoke treatment.
- Patients were under the care of the same doctor throughout their course of treatment, including when they received their check-ups.
- Reasonable adjustments had been made so that people could access and use services on an equal basis to others. We saw patient feedback where patients could only attend evening appointments were accommodated.

## Timely access to the service

**Patients were able to access care and treatment from the service within an appropriate timescale for their needs.**

- Patients had timely access to initial assessment and diagnosis. However, we were not assured tests and treatment were always on time due to the gaps we found between testing in 8 of the 10 patient records we reviewed.
- Patients with the most urgent needs had their care and treatment prioritised.
- Online feedback we viewed showed patients reported that the appointment system was easy to use and the service offered evening appointments. Patients also described their experience of accessing care as efficient, thorough and professional. Patients also reported the service was extremely responsive and emails were responded to within an hour.

## Listening and learning from concerns and complaints

**The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.**

- Staff treated patients who made complaints compassionately.
- The service had complaint policy and procedures in place and they informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service told us they learned lessons from individual concerns, complaints and from analysis of trends and would act to improve the quality of care.

## Are services responsive to people's needs?

- The provider told us they had only received one complaint since the last inspection, where the patient felt the consultation was rushed. This complaint was resolved after discussion with the patient and the clinician.

# Are services well-led?

At the last inspection we rated well-led as inadequate because:

- The service had a clear vision but the values in place did not support a credible strategy to deliver high quality care and promote good outcomes for patients.
- There were gaps in governance processes.
- There was no clarity around processes for managing risks, issues and performance.
- The service did not always act on appropriate and accurate information.

At this inspection, there had been some improvement in the provision of well-led services and we rated the provider as requires improvement for providing well-led services because:

- Although there were still gaps identified at this inspection, they had addressed some of the breaches of regulation from the last inspection, particularly recruiting a consultant dermatologist and creating a joint strategy to deliver effective care.
- There were gaps in good governance.
- There were no effective processes for managing risks, issues and performance.

## Leadership capacity and capability;

**Leaders had the capacity and skills to deliver high-quality, sustainable care; however further improvement was required.**

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them; for example, they had addressed the inspection findings from our last inspection and addressed some of the breaches of regulation that had been highlighted in the Warning Notice.
- Leaders at all levels were available remotely and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership. There was a clear reporting structure with all staff having access to the registered manager.
- The provider had processes to develop leadership capacity and skills; however, they did not provide information regarding any succession planning of the service.

## Vision and strategy

**The service had a clear vision and were working to ensure they had a credible strategy to deliver high quality care and promote good outcomes for patients.**

- Staff were now part of a consultant led team, following the recruitment of a consultant dermatologist for the service. They developed a strategy to improve the quality of care and outcomes for patients. As they were in post for two months, their strategy was not yet embedded in the service and will be assessed at the next inspection.
- The provider had a clear vision of their business strategy but improvement was required to ensure they had an effective and credible strategy to promote good outcomes for their patients by following national guidelines when assessing and delivering treatment. The role of the newly recruited consultant dermatologist was to ensure this strategy would be followed.
- The service developed its vision, values and strategy jointly with staff who were aware of and understood the vision, values and strategy and their role in achieving them.

## Culture



# Are services well-led?

**The service had a clear vision and they had a strategy to deliver high quality care and promote good outcomes for patients.**

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. We also found the provider was open and transparent when discussing the service and any gaps we identified.
- The provider was aware of the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There was a strong emphasis on the safety and well-being of all staff; however, completed health and safety risk assessments for remote workers were not provided.
- The service actively promoted equality and diversity. The provider sent evidence of equality and diversity training for staff following the inspection. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

## Governance arrangements

**There were gaps in governance; however, clear responsibilities, roles and systems of accountability to support good governance and management were being established.**

- We saw evidence that since the last inspection, the provider had taken steps to improve their governance arrangements; for example, there was now a system for verifying the identity of patients, ensuring there was a named safeguarding lead and clear indemnity arrangements. However, further improvement was still required to ensure systems in place were robust as we continued to find gaps in the structures, processes and systems to support good governance. This was in relation to gaps we found in mandatory training, such as health and safety and information governance or data protection for some staff.
- At this inspection, we were not assured staff were clear on their roles and accountabilities in relation to ensuring their Isotretinoin prescribing practice was carried out as per the national recommended guidelines. We continued to find that clinicians failed to refer patients to psychiatrists where they disclosed a history of mental health conditions as per the national guidance.
- There were arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.
- Leaders told us they had established proper policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. We saw evidence of their recently updated Isotretinoin prescribing processes, safeguarding policy and other operational policies within the service, such as the mandatory training and complaints policy.

## Managing risks, issues and performance

**Further improvement was required to ensure clear and effective processes for managing risks, issues and performance.**

- There was improvement in some of their systems to identify, monitor and address current and future risks; however, this was not sufficiently demonstrated due to gaps in overall risk management. For example, whilst we saw improvements relating to the pregnancy prevention programme and we saw that the newly recruited consultant

# Are services well-led?

dermatologist, currently undergoing induction had carried out an initial audit of the Isotretinoin prescribers consultations and developed a joint action plan with the provider at the time of inspection, further action was required to ensure they addressed the risk relating to not actioning abnormal test results such as for their cholesterol levels, which placed patients at risk of harm due to poor monitoring processes.

- Individual health and safety risk assessments relating to remote workers were not carried out, to ensure they were working in safe environments.
- Although performance of clinical staff could not be demonstrated through documented clinical supervision, the consultant dermatologist and the provider had put in place processes via their joint action plan to manage current and future performance. Performance of clinical staff would be demonstrated through audit of their consultations, prescribing and referral decisions, where cases would also be escalated to the consultant dermatologist. The provider told us staff received annual appraisals and clinicians we spoke to received annual NHS appraisals and were up to date with their revalidation, we saw evidence to support appraisals were taking place at this inspection.
- We saw that leaders had oversight of safety alerts, incidents, and complaints. However, the provider did not share evidence relating to significant events as there had not been any since the last inspection.
- The provider had a business contingency plan in place and we saw evidence that it was shared with a staff member. However, it was not clear if it was shared with all other service staff.
- When we discussed our findings with the consultant dermatologist and the provider, they agreed guidance was not being followed in these areas. Following our findings, the consultant immediately amended their Isotretinoin policies and procedures to reflect and ensure the assessment and provision of care would be delivered according to the national guidelines. We discussed what the consultant dermatologist's role would entail and the provider and consultant developed a joint action plan that the consultant's role would be to:
  - not review all patients but would be available to assess and advise on any patients the doctors escalated to the consultant for input.
  - review, modify as appropriate and sign off on the Botonics Isotretinoin policies and procedures.
  - join quarterly Isotretinoin staff meetings when possible, or review the minutes of these meetings.
  - audit and document at least 1% of patients under care to assess whether their care has complied with the service's policies and procedures on a quarterly basis.

## Appropriate and accurate information

### The service did not always provide appropriate and accurate information.

- Performance information was combined with the views of patients.
- The provider introduced quarterly meetings and staff could communicate via their WhatsApp group messaging where they had access to information.
- The service submitted notifications to external organisations as required.

## Engagement with patients, the public, staff and external partners

### The service involved patients, the public, staff and external partners to support high-quality sustainable services.

- The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them to shape services and culture.
- Staff could describe to us the systems in place to give feedback and they told us they had opportunities to provide their own feedback. We also saw staff engagement in responding to findings, such as the previous CQC inspection report.

# Are services well-led?

- The service was transparent, collaborative and open with stakeholders about performance.

## **Continuous improvement and innovation**

### **There was some evidence of systems and processes for learning, continuous improvement and innovation.**

- There was some focus on continuous learning and improvement and we saw they had placed some systems in place to support improvement following our inspection report; however, we continued to find gaps in these systems.
- The service made use of internal and external reviews of incidents and complaints. Learning was shared and used to make improvements.
- Leaders and managers encouraged staff to take time out to review individual and team objectives, processes and performance.

## Requirement notices

### Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <ul style="list-style-type: none"><li>• There was a lack of systems and processes in relation to, actioning of abnormal test results and taking further action where patients disclosed a history of mental health problems.</li><li>• Blood test monitoring did not always occur at the recommended intervals.</li><li>• There was no evidence of formal health and safety risk assessments for remote workers.</li></ul> <p><b>This was in breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</b></p>
Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 18 HSCA (RA) Regulations 2014 Staffing</p> <ul style="list-style-type: none"><li>• There were gaps in mandatory staff training. Not all staff were up to date with information governance or data protection training, as one last completed this training in 2016.</li><li>• Staff had not received health and safety training.</li></ul> <p><b>This was in breach of Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</b></p>