



# The NHS Low Calorie Diet Programme Referral Toolkit

# A summary of key resources for health care professionals to support referrals

Download this document and either save to a diabetes folder in your mailbox or print a copy for reference

Full resources are available to view and download on our <u>Team Net</u> web page. <a href="https://teamnet.clarity.co.uk/Topics/ViewItem/d40a1086-6cb5-4ac5-9963-ae6100a96576">https://teamnet.clarity.co.uk/Topics/ViewItem/d40a1086-6cb5-4ac5-9963-ae6100a96576</a>

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## The NHS Low Calorie Diet Programme Why should my practice take part?



It offers my patients the chance of putting their type 2 diabetes into remission

46%

Remission achieved in LCD participants in RCTs



The programme is free with no costs for participants. Including 3m of total diet replacement products e.g. soups and shakes.

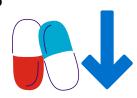




Patients are monitored on the programme. You will be alerted with clear actions if NHSE thresholds are breached.



Patients are likely to no longer need diabetes related medications or significantly reduce their medications.



All CBG monitors and testing strips required for the duration of the programme are provided free of charge with no costs to the practice.



Due to the more conservative approach to medication adjustments (compared with clinical trials), far fewer retitrations are seen in this programme.



**12** 

Months of ongoing education and support to help your patients lose a significant amount of weight and potentially achieve remission of their Type 2 diabetes.

Patients on existing programmes often visit their GP less. This may be because of trained coaching and peer support as well as a reduction in weight/diabetes related ill health.



Support to sustain weight loss and remission of type 2 diabetes for the long term.



# The NHS Low Calorie Diet Programme Who is eligible?



#### Inclusion Criteria

Aged between 18 - 65 years inclusive

Diagnosed with Type 2 diabetes within the last 6 years

BMI of ≥ 27kg/m2 (adjusted to ≥ 25kg/m2 in people of BAME origin)

Engaged with diabetes care:
Attended mornitoring and diabetes
review when last offered, incl,
retinal screening, (or willing to
attend before referral) and commit
to continued annual reviews, even
if remission achieved.

HbA1c within 12 months, with values as follows:

- If on diabetes medication, HbA1c ≥ 43mmol/mol (6.1%)
- If not on diabetes medication, HbA1c ≥ 48mmol/mol (6.5%)
   In all cases, HbA1c must be ≤ 87mmol/mol (10.1%)

#### **Exclusion Criteria**

Current Insulin user

Currently breastfeeding

Pregnant or planning to become pregnant within the next 6 months. Note: weight loss may cause fertility to return.

Has at least one of the following co-morbidities: active cancer; heart attack or stroke in the last 6 months; sever heart failure (New York Heart Association grade 3 or 4); severe renal impairment (most recent eGFR<30mls/min/1.73m2); history or presence of liver disease (not including NAFLD); active substance use disorder; active eating disorder; Porphyria; or known proliferative retinopathy that has not been treated.

Gallstones do not automatically exclude. However, patients and clinicians need to be aware that rapid weight loss can exacerbate underlying issues. Large or small gallstones, may be less problematic than medium sized stones.

Significant unintentional weight loss (>5% body weight) within last 12 months or currently on a weight management programme.

Unintentional weight loss of more than 5% may exclude. Exceptions may be if the GP is happy that there is no other sinister cause and they are happy for the patient to commence the programme.

If patients would like to exit the current weight management programme they are on, then they may be

eligible.

Had/awaiting bariatric surgery (unless exits waiting list)

Health professional assessment that patient is unable to understand or meet the demands and/or monitoring requirements of the NHS LCD Programme; or for whom the programme is not appropriate clinically (consulting with relevant Specialist teams if required); or for whom safe and robust medications adjustment is not practical in a primary care setting.



# The NHS Low Calorie Diet Programme The Patient Journey



#### **Rescue TDR Package Referral: Primary care** Phase 1: Reboot If 2kg or more weight gain Shortlisted and invited by **Total Diet Replacement (TDR)** • TDR provided for 4 or 6 text/letter/call • 12 weeks weeks • Interested patients contact practice • 8 sessions: 1 individual, 7 group • Mini or full reset plan • Suitability confirmed and medications **Primary Care Primary Care** • Chosen TDR products delivered reviewed • Repeat HbA1c at 6 • Repeat HbA1c at monthly • Referral completed and medications and 12 months 6 and 12 months Comprehensive resources: adjustment form given to patient and • Medication/other Medication/other Workbook, lifestyle logbook included with referral form (RAMAF) reviews if required reviews if and recipe book required Phase 2: Rebalance Registration and IA **Food Reintroduction** • Momenta contact and • 6 weeks Signposting Phase 3: Retune check eligibility within 5 • 4 sessions: 1 individual, 3 • Ongoing & discharge Maintenance davs group NHS and other national • To 12 months • Individual assessment Chosen TDR products tools • 9 group sessions (40mins) • Local partners and delivered

Pedometer

• Book onto programme

• 1 group session

Fibre

Exi app



pathways

## The NHS Low Calorie Diet Programme Frequently asked questions



#### 1. Does the programme cost anything for patients?

No, the programme is completely free, including the provision of meal replacement soups and shakes. As groups are in-person at community venues patients may incur some travel costs.

#### 2. Is the programme suitable for people with special diets?

The range of soups and shakes is provided by the company Exante. There are options to suit vegetarians, vegans and those who are gluten free.

#### 3. Where will the in-person group sessions be located?

Group sessions are typically held at accessible community venues within 5 miles of the practice. In rural locations this distance may be longer but usually not more than a 20 minute drive from the practice.

We welcome your suggestions of suitable local venues, which should meet the following criteria, adjusting for urban / rural locations:

- Room with comfortable space for up to 15 seated participants (some with occasional accompanying partners)
- Good local public transport links (and parking if appropriate)
- Clean and appropriately lit and heated/ cooled throughout the year
- Meet accessibility requirements (ground floor access or lifts, nearby appropriate toilet)
- Meet Covid guidance in place at the time

#### 4. Can patients have a break during the total diet replacement (TDR) phase of the programme?

The TDR phase is challenging at the best of times. Side-effects and special events e.g. birthdays or weddings can exacerbate difficulties. . The service supports participants in a number of ways, including swapping a TDR product for a small vegetable-based meal or eating real food for a special event meal / day.

#### 5. Can patients consume alcohol while they are on the programme?

Yes, however not during the initial 12-week total diet replacement phase.

#### 6. How long is the programme?

The programme lasts for 12 months, including 21 in-person group sessions. Sessions are more frequent over the first two phases (weekly then fortnightly), moving to monthly for the remainder of the programme.

## The NHS Low Calorie Diet Programme Frequently asked questions



#### 7. Once a patient has been referred, how long does it take to start the programme?

After referral (with complete documentation) participants can expect a welcome call from the provider (Momenta) within 5 working days. Momenta will carry out an initial assessment, including confirming eligibility and that the participant has a copy of their medications adjustments form (even if no adjustments are needed). Patients will then be offered a choice of programmes (different locations, days and times), usually within 2-4 weeks if the patient is referred in the practice cohort time frame (otherwise the wait could be much longer).

#### 8. Are there any side effects?

Occasionally, TDR programmes may cause side effects. In most cases these are temporary and simply caused by a lower energy intake. Common side effects include constipation, headaches, fatigue, irritability and sensitivity to cold. Momenta health coaches are trained to support participants to manage these and fibre supplements are provided to all individuals at the start of TDR to prevent constipation. However, if symptoms persist then Momenta's MDT (including GP Medical Director) will discuss directly with the individual and potentially the individual's practice team to ensure appropriate action is taken.

#### 9. How are patients monitored during the programme?

As well as significant side-effects and adverse events the Momenta health coaches collect weight, blood glucose and blood pressure (if required to monitor BP) measurements at group sessions. All readings outside of NHS England thresholds, as well as any adverse events or significant side-effects are reviewed by the Momenta MDT. Momenta will notify or alert the practice (including same day contact if appropriate) and advise the patient how to proceed. Any practice actions will be highlighted clearly).



### The NHS Low Calorie Diet Programme Information for patients



#### What is it?

A new 12-month low calorie diet treatment for people who are overweight and living with Type 2 diabetes in Somerset.

The programme has three phases.

#### Who is it for?

You must be registered with a GP practice in Somerset and:

- Be aged 18-65 years
- Have had a diagnosis of Type 2 diabetes within the last 6 years
- Have a BMI over 27 kg/m2 (or over 25 kg/m2 if you are of Black, Asian or minority ethnic origin).

You also need to meet various other eligibility criteria and be willing to commit to the 12 month group programme to be referred

to the service.

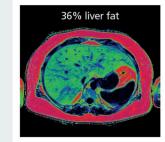
#### How does it work?

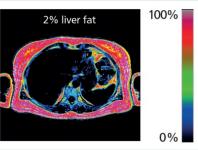
The programme is based on the DiRECT study which showed this approach could help people lose weight, improve their diabetes control, reduce diabetes-related medication and even achieve remission (whereby blood glucose levels return to normal without the need for medication). Significant weight loss as quickly as safely as possible following your diagnosis appears to be important for achieving remission. Low calorie diets can remove excess fat from vital organs, such as the liver

and pancreas, which can result in them working normally again, putting your Type 2 diabetes into remission.

#### Phase 1 Phase 2 (12 weeks) (6 weeks) (7-8 months) To start you'll follow a low You'll then gradually Finally you'll receive calorie diet (soups, shakes, replace these products ongoing support to help bars totalling 8-900 calories with real meals over six you maintain your weight per day). weeks.

## MRI scan on left shows % liver fat ( area in green) of a participant in DiRECT before starting the low calorie diet. MRI scan on the right shows the same liver after 8 weeks on the low calorie diet.





#### Want to know more?

#### Visit the Momenta website:

https://momentanewcastle.com/patient-lcd-somerset to find out more about the programme, whether the programme is right for you and when it will be available in your area. Alternatively, please scan the QR code on the right.



#### **Programme Features**



 No cost to participants, includes all meal replacement products



• Group in-person sessions delivered at local community venues



12 months of regular support from trained diabetes health coaches



 Free resources including recipe books, work and lifestyle log books, pedometer and more...



• Learn skills and techniques to help keep the weight loss off for the long term



 Reduce blood glucose levels and potentially achieve remission of your diabetes

# The NHS Low Calorie Diet Programme Information for patients



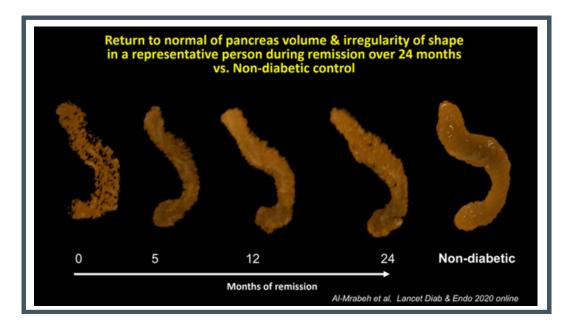
#### Low calorie diets have shown to remove excess fat from vital organs such as the liver and pancreas

Low calorie diets can result in rapid and significant weight loss, important for achieving remission of Type 2 Diabetes

The liver MRI scans to the right are taken of the liver from a participant in the DiRECT low calorie diet clinical trial. The image on the left shows % liver fat before commencing the programme. The image on the right was taken 8 weeks into the total diet replacement phase of the low calorie diet programme. Here you can see the dramatic reduction of fat within the liver.

36% liver fat 2% liver fat 100% 0%

The MRI images to the right are taken of the pancreas from a participant in the DiRECT low calorie diet clinical trial. As the programme progresses, the pancreas increases in size (by approx 20%) and becomes more regular in shape, resembling a more normal pancreas at 2 years.







# NHS Low Calorie Diet Programme

# Summary operating procedure

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1 ENIIS Sparch - porform an ENIIS coarch toing sparch to and Vide	There are three main ways to identify eligible patients:
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2	
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- perrorm an EIVII'S search using <u>search template</u> and <u>Video guide</u>
- 2. Opportunistically engage with patients during annual reviews or if increasing or considering starting medications.
- 3. Advertising putting up posters in the practice or digital posters on the practice website. Sharing with patient participation groups

## 2. Invite

accompanying LCD leaflet with the invite Invite eligible patients using the EMIS template letters or texts. Enclose the

# 3. Confirm suitability

It is the responsibility of the referrer to:

- Discuss the programme with patient
- Confirm the patient meets all eligibility and exclusion criteria.
- group sessions is required to achieve the full benefits. Consider readiness tool. Assess the patient's motivation to take part in the programme highlighting commitment for the full 12 months and attendance at approx 20 in-person
- Provide information on concept of remission of Type 2 Diabetes, the LCD service and potential risks and benefits to obtain informed consent.

programme, they will do the following: The referrer should also confirm with the patient, should they commence the LCD

- Agrees to continue attending yearly diabetes review appointments at their GP practice, regardless of whether remission is achieved.
- Will notify their GP practice of any unexpected or concerning symptoms
- Will notify their GP practice if they disengage or drop out before the end of
- Attend for 6 and 12 month HbA1c monitoring and review

# 4. Complete referral and medications adjustment form

- minute recorded video from the LCD education session. guidance on medications adjustments see the NHSE guidance document and 15 Complete EMIS template referral and medications adjustments form. For
- this form and confirm they understand it, even if they are not on medications Discuss medications adjustments with patient and ensure a written copy of the and/or are making no adjustments Provider cannot accept patients onto the programme unless they have a copy of medications adjustments is given to the patient. Note: For safety reasons the
- Provider delivering the programme) via NHS email to: somicb.LCD@nhs.net. Email completed referral and medications adjustments form to Momenta (the



# 5. Pre-assessment • Momenta will a and book onto • Patient will be

Momenta will contact patient within 5 days, complete an individual assessment and book onto the programme (usually starting within a month of referral).

Somerset

Patient will be invited to attend a pre-programme group session including be monitored at group sessions) education on self monitoring of blood glucose (blood pressure and weight will

# 6. LCD 12 month programme

Patient attends 12 month programme consisting of 3 phases:

- 1. Total Diet Replacement (TDR) 12 weeks total diet replacement products are fortnightly group sessions, and one individual session. chosen by patient and delivered monthly. Patient attends weekly then
- 2. Food Reintroduction 6 weeks Patient attends three group sessions and one individual session to support with reintroduction of regular healthy food.
- 3. Maintenance 7-8 months patient attends nine group sessions to support with weight maintenance. A TDR 'reset plan' is available for those who regain weight.

# Momenta LCD provider will:

- Monitor blood glucose, blood pressure (for those on blood pressure medications appropriate if action is required. at referral), side affects and adverse events, reporting back to GP where
- programme (including completion) with recommended SNOMED codes Report back to GP when participant reaches various milestones

# GP requirements during the 12 month programme are:

- Respond to any clinical need to further adjust medications, communicated from threshold breaches. the Provider, for capillary blood glucose and blood pressure monitoring
- clinical need or is directed to the GP practice by the Provider. Respond to adverse events if patient contacts practice directly with an urgent
- Review patient at 6 months and 12 months after starting LCD programme with repeat HbA1c with further medication adjustment as necessary.

# 7. Remission status

# GP Requirements following completion of the programme are:

enable QOF recognition to continue. DO NOT use the code 'Diabetes Resolved' guidance from NHSE. Ensuring those who achieve remission are coded as 'Type 2 Confirm whether remission of Type of type 2 diabetes is achieved using the Diabetes in Remission' (703138006) - to keep patient on the diabetes register and

Continue to offer routine monitoring and review as per usual care for Type 2

Diabetes. Note: 'Active Type 2 Diabetes' may return if weight is regained

# 8. Key Contacts

- Lesley Harper Project Officer Lead for LCD programme lesley.harper1@nhs.net
- Jon Scott Momenta Newcastle Manager jon.scott@momentanewcastle.com\_01823

Visit our Team Net LCD or Momenta's HCP websites for more information



## The NHS Low Calorie Diet Programme Medications adjustments guidelines overview



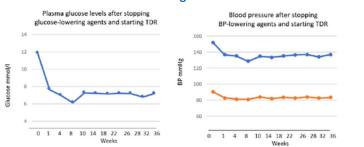
This is an overview only – it MUST to be read alongside the background and detail in 'Guidance for GP practices and referrers' (NHSE & NHSI 30/11/2021 v2)

Click here to view the full NHSE guidance document

#### The three phase NHS Low Calorie Diet (LCD) programme is based on evidence from the DiRECT and DROPLET studies

- People aged 18-65 with Type 2 DM within 6 years of diagnosis meeting other eligibility criteria will receive total diet replacement (TDR) products for 12 weeks, followed by 6 weeks of Food Reintroduction and Weight Maintenance support to 12 months. **Patients are required to attend 21 group sessions** led by a Dietitian or Nutritionist to facilitate learning and behaviour change.
- At referral, general practice must instruct patients to adjust their glucose-lowering and BP-lowering medications on Day 1 of TDR by providing them with a **Medications Adjustment Form (MAF), copying the MAF to the Provider for information**. The referring practice remains responsible for patients' medications. The Provider monitors weight, blood glucose and blood pressure for those on BP medications at referral, informing general practice if certain thresholds are exceeded
- Further evidence-based and pragmatic guidance is set out in 'Guidance for GP practices and referrers document' (30/11/2021 v2) developed by an NHS England Expert Advisory Group. These recommendations do not replace clinical judgement and constitute guidance only. This page is a simplified summary only.

### Counterbalance study findings (informed DiRECT) Steep BG reduction in 1 week of TDR Lower reduction in BP - after stopping ALL agent



#### NHS LCD Programme approach to blood glucose (BG) and blood pressure (BP)

- Based on DiRECT, but more conservative
- Patients are not at risk of hypoglycaemia as relevant medications must be stopped on day 1 of TDR\*
- Adjust only ONE BP-lowering agent initially (DiRECT stopped all)
- GP practices to repeat HbA1c at 6 and 12 months after programme start

#### Provider monitoring and GP practice notification / contact

- Frequency: Weekly/fortnightly on TDR, otherwise monthly
- Blood glucose (mmol/l): Notify GP practice if 15.0-19.9 over 2 sessions; Same day contact if ≥20.0
- Blood pressure (mmHg): Notify GP practice if <=89/59 or postural symptoms or 160/100 to 179/119; Same day contact if ≥180/120 or postural symptoms interfere with daily activities

#### \*\*\*\*\*\*\*\*\*Patients must be instructed to adjust medications on Day 1 of TDR\*\*\*\*\*\*\*\*\*

#### Medication adjustment recommendations – Blood pressure-lowering agents

- Uncontrolled BP (≥140/90mmHg either sys or dia): No change
- Controlled BP (<140/90mmHg both sys and dia): Adjust one BP-lowering agent. Identify agent(s) specifically and solely for managing BP and stop the agent added last according to NICE Guidance (NG136 (2019))
- If any BP medication is used for other indications use clinical judgement, cautiously reduce and monitor more closely
- Counsel patient about postural hypotension symptoms / seeking support
- Medicines prescribed for other indications can also affect blood pressure e.g. tamsulosin for BPH, furosemide for oedema and ACE-inhibitors for heart failure etc. See Guidance document for detail
- Subsequent adjustment: BP too low repeat above; BP too high restart/uptitrate

#### Medication adjustment recommendations - Glucose-lowering agents

- People on 1-2 agents (most patients): STOP all
- People on ≥3 agents: STAY on metformin only, STOP other agents. (If metformin contraindicated / not tolerated see guidance)
- Counsel patient about osmotic symptoms / seeking support
- Sulfonylureas, meglitinides and SGLT2 inhibitors are not safe with TDR and MUST be stopped; and insulin is an exclusion criteria
- Restarting agents: See detailed guidance p27

#### Medications needing adjustment - weight / dietary changes

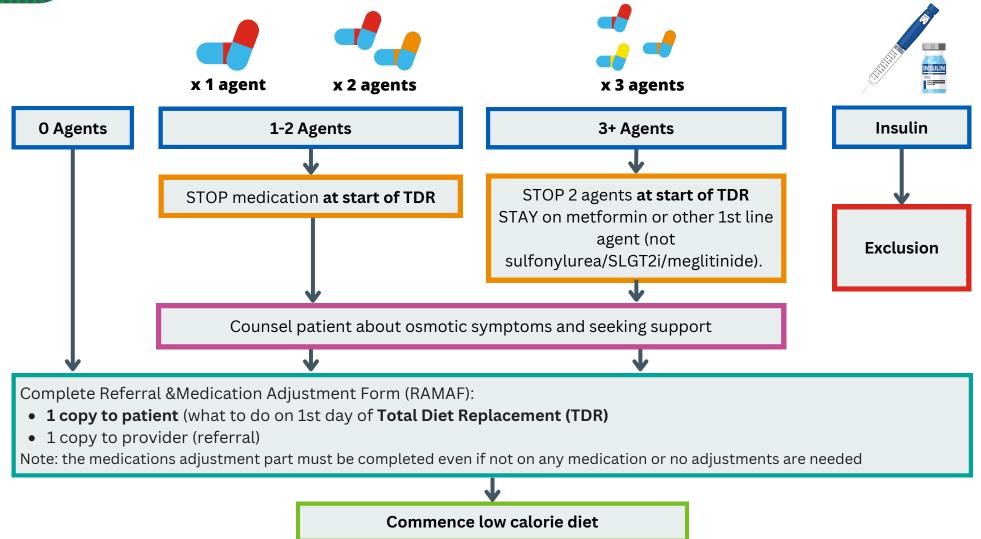
- Some medications may need adjusting due to changes in body weight or dietary intake e.g. warfarin, NOACs, antifungals (see guidance for others)
- Some may be prescribed by other services and not on GP IT systems
- Always ask patients if they are receiving other treatment
- If in doubt discuss with a pharmacist





## The NHS Low Calorie Diet Programme Diabetes glucose medications overview (<6yrs T2DM)





#### Glucose monitoring at all group sessions:

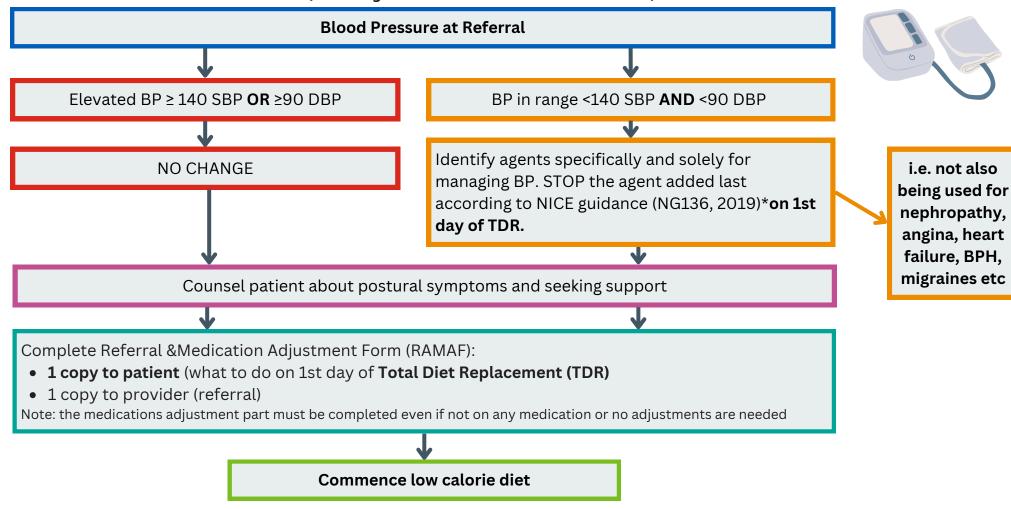
- Under 15 mmol/l: No action
- Between 15.0 19.9 mmol/l over 2 Sessions: Provider must contact the Service User's GP practice
- 20.0 mmol/l or higher: Same-day contact with the Service User's GP practice team (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day)



### The NHS Low Calorie Diet Programme Blood pressure medications overview



(Including medicine used for other indications)



#### BP monitoring at all group sessions (for those on BP lowering agents at referral)

- SBP<90 or DBP<60 ot postural symptoms reported: Repeat above process
- SBP 160-179 OR DBP 100-119: Increase or uptitrate as per NICE Guideline
- SBP ≥180 OR DBP ≥ 120: Same day contact with GP practice. Increase/uptitrate per NICE

<sup>\*</sup> Order of stopping first: (i) Spirinolactone or alpha blocker or beta blocker (ii) Thiazide diuretic or calcium channel blocker (iii) ACE inhibitor or Angiotensin receptor blocker

